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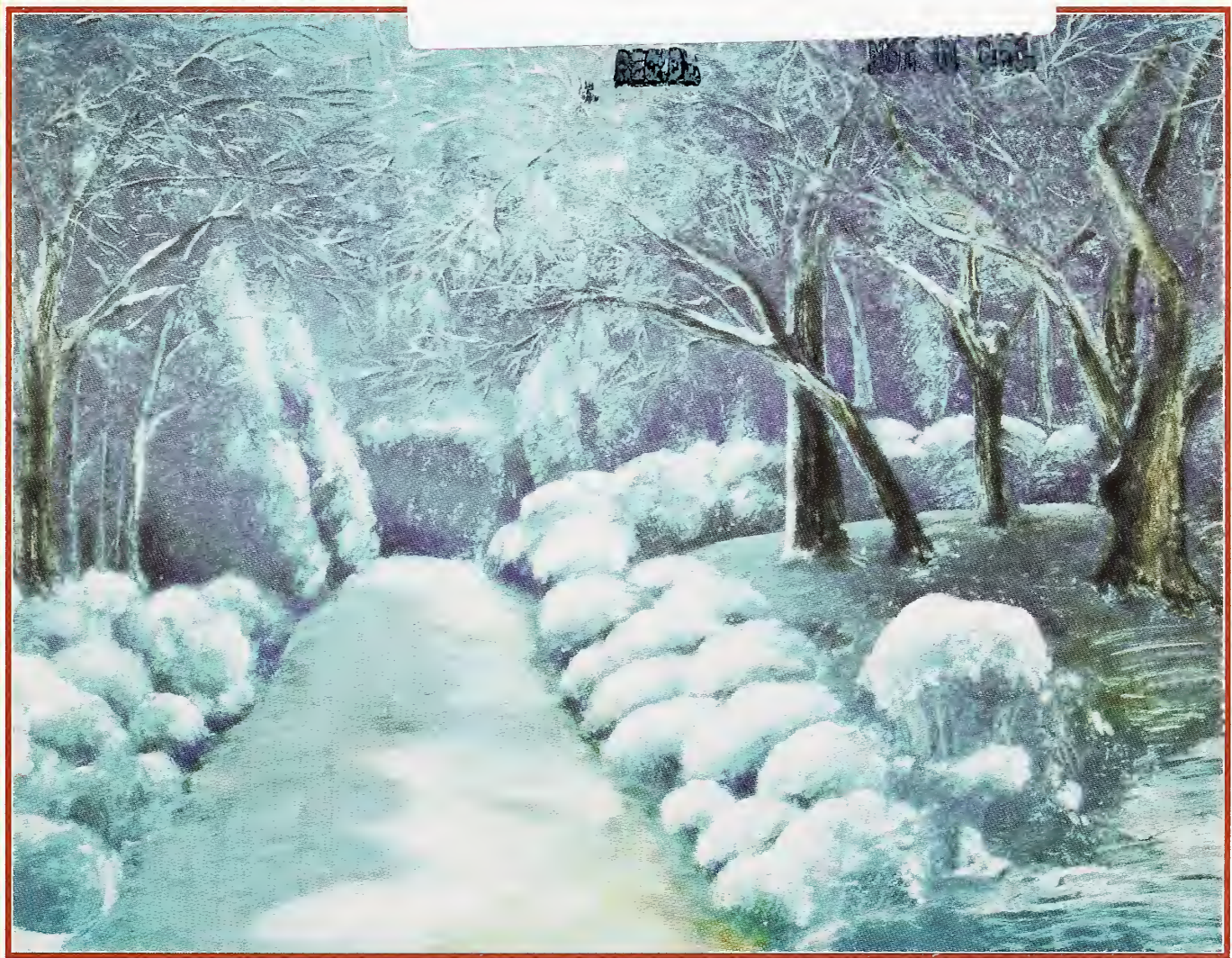
RHODE ISLAND

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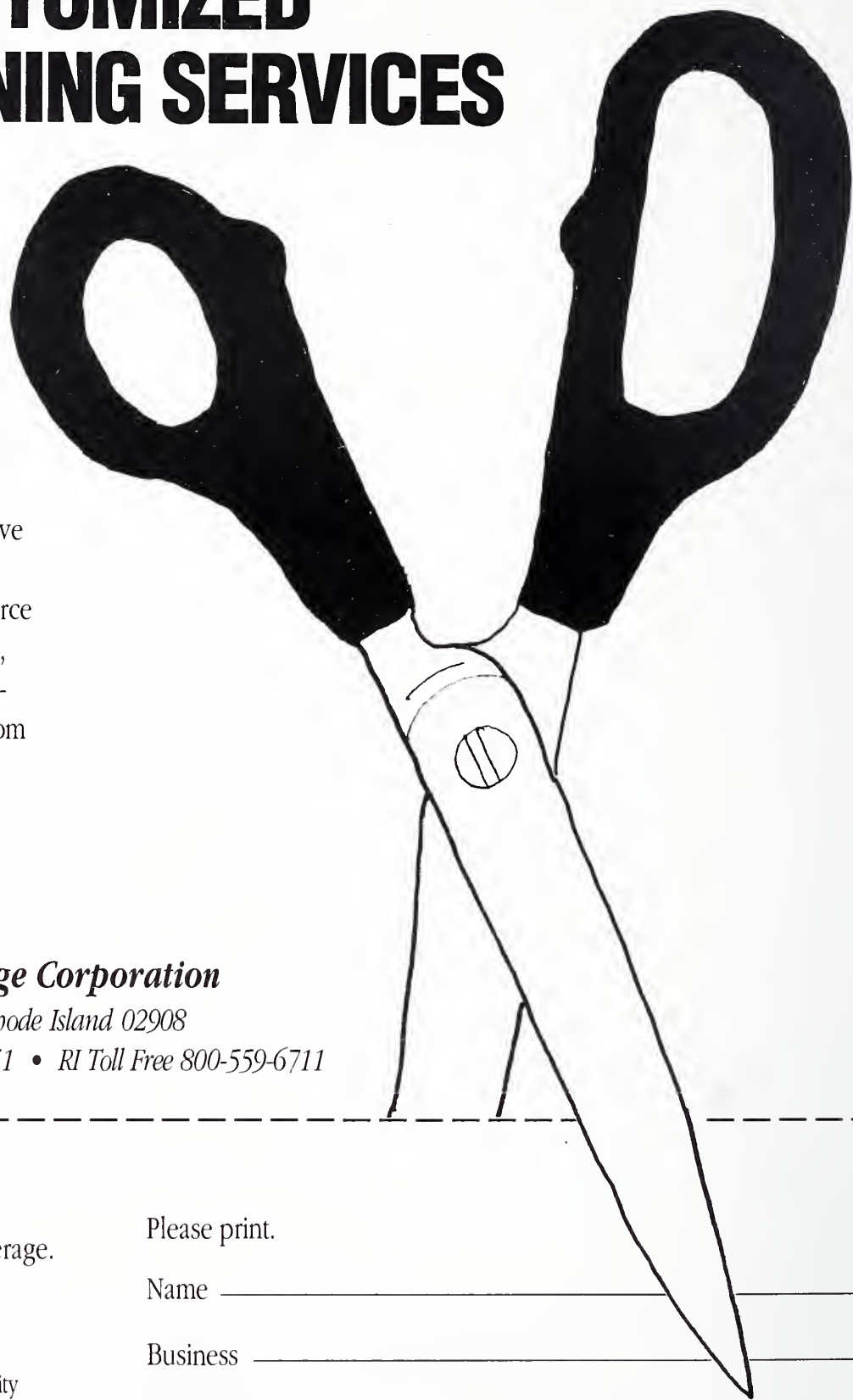
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Conflict and Contagion

War, said Sherman, is hell. As a moral lesson the statement has certainly been quite ineffective since warfare continues unabated.

Texts tend to condense Sherman's observations to a brief summation. His fuller text, given 14 years after the completion of the Civil War, was: "I am tired and sick of war. Its glory is all moonshine. It is only those who have neither fired a shot nor heard the shrieks and groans of the wounded who cry aloud for blood, more vengeance, more desolation. War is hell." He might have added that the hazards of war extend beyond flying shells and bullets; and that death from dysentery, the chief cause of military casualties during Sherman's military career, was no less hellish.

Sherman's bitter comments reflected his many years of intimacy with the dirty undersurface of warfare. Wars may be won by bold strategies, superior arms and disciplined armies; but beyond the heroics and beside the heat of battle lie the equally imperative factors of efficient supply lines as well as a respectful regard for the perils created by contagious disease. Bismarck accredited his victories in the

Franco-Prussian War as much to his medical corps as to his cavalry.

The rigors of military life place great strains upon the established sanitary systems; and when troops are then engaged in desperate battle, the urgencies of confronting the visible perils will always take precedence over avoiding the invisible, microbiological menaces. If one nation therefore zealously guards the health of its combatants while the opposing army does not [as was the case during the Russo-Japanese War] victory may well be achieved by the smaller army.

Military commanders who strive to identify those elements which determine victory [beyond, of course, their own charismatic leadership] have quickly recognized the strategic importance of vigorous and uninterrupted medical support. In combat, where excessive crowding, contaminated water supplies and primitive sanitary facilities prevail, any lapse in standard public health precautions will inevitably lead to widespread and disabling respiratory and enteric infections amongst the troops.

The Parliamentary report describing the casualties in British troops engaged in the Crimean Peninsula War [1854-56] - prepared by Florence Nightingale - told a grim and sobering story. Of 18,058 deaths in the combat



zone, only 1,890 were secondary to enemy fire; the remainder, fully 90%, were caused mainly by infectious diseases particularly dysentery and louse-borne typhus. In the Boer War [1899 - 1902] non-combatant casualties in the British army were fivefold greater than deaths caused by enemy action. And during World War I, historians estimate that over one million troops on the eastern front succumbed to typhus during a three year span. Truly, the greater enemy has been microbiologic.

Reports from the US Surgeon General's Office provide essentially similar data. In the Mexican War of 1846-48, for example, seven out of eight deaths [87%] were attributed to infection rather than the hazards of direct combat. By the Viet Nam War, this fraction had dropped to 19%. Indeed of every 100 soldiers inducted into the American armed forces in the 1846 conflict, close to 15 died of some cause other than battle field injury, typically infection. During the Viet



War	Non-combatant Deaths [%]	Non-combatant Deaths as % of Total Personnel
Mexican War	87.0	14.7
Civil War	61.6	10.4
World War I	52.5	1.3
World War II	26.2	0.7
Viet Nam War	19.0	0.1



Nam War, in comparison, only one inductee in a thousand died of infection. The accompanying table also illustrates that World War II was the first time in the military history of this nation that non-combat events [largely infectious disease] assumed a secondary role as the cause of casualties.

In 19th Century armies, measles represented a measureable risk particularly when young recruits from rural communities,

never previously exposed to measles, were clustered in induction centers. To understand the full impact of measles upon combat capability, consider the following: In the Union armies, during the Civil War, slightly over 3% of all fresh recruits contracted measles each year, with a 2% case fatality rate. The Union army had numbered about 2.1 million men in uniform. Each year during the war, in addition to those dying of the disease, measles incapacitated about 63,000 soldiers for intervals up to a month. At any one time, hence, measles morbidity deprived the Armies of the Republic of 5,000 soldiers.

The declared purpose of war, whether it be the advocacy of some laudable principle, the defense of the homeland or the consuming urge to conquer someone else's homeland, requires the fulfillment of but one objective: the defeat of

the enemy, by whatever means. But both sides in a conflict, in a sense, become losers. Victory then is reserved for the side with fewer losses - whether achieved through decisive battle or by superior hygienic measures.

The full horror of war - Sherman's hell - cannot be appreciated, then, unless the appalling results of poor sanitation and rampant contagion are also addressed. Infectious disease has always been an intimate accompaniment of warfare. Occasionally, though, it has assumed the dominant role as in the 16th Century Spanish conquest of Mexico when smallpox selectively decimated the ranks of the immunologically innocent Aztec armies.

— Stanley M. Aronson, MD

Scientific Contributions by Medical Students and Resident Physicians

The recent tables of contents of Rhode Island's state medical journal reveal an interesting trend: the number of scientific articles submitted for publication, written by Brown medical students or by Brown University-affiliated hospital resident physicians, has increased dramatically. Prior to 1972, of course, there had been no medical school in Rhode Island; furthermore, the number of house staff in the eight hospitals affiliated with the medical school 25 years ago had been but a fraction of today's complement of resident physicians. Indeed, in recent years, over one-fourth of the articles appearing in this publication have one or more authors who are either students or resident physicians.

In recognition of this trend, *Medicine & Health/Rhode Island* is assigning its January, 1998, issue to the instructive manuscripts submitted by Rhode Island's students or physicians in supervised training.

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Save the Date



Bicycle Helmet Protection in the Fox Point Community

Michael A. Posencheg, AB, Michael Chen, AB, Christopher Healey, AB,
Phillip Lai, AB, and Scott D. Berns, MD, MPH

The need to promote bicycle helmet use exists because of the severity and scope of bicycle-related head injuries. Eight to nine hundred Americans die of bicycle-related injuries each year, according to the Bicycle Helmet Safety Institute. Approximately 75% of the fatalities are due to head injuries and 66% of them occur in children.² In Rhode Island, for the one-year period ending April 30, 1996, bicycle accidents were the third leading cause of injury for emergency room visits that resulted in hospital admissions in children under 18 at Rhode Island Hospital. Bicycle accidents were third only to motor vehicle accidents and falls.⁵ Bicycle riders without head protection are roughly three times more likely to suffer head injuries in a crash than those who wear a helmet, and bicycle riders who suffer head injuries are twenty times more likely to die than riders who suffer other types of injury.¹ As the number of bicycle riders increases in the United States, these data justify a serious public health concern and also support the use of helmets to prevent both injury and death.

Bicycle helmets have been proven to prevent both injury and fatalities. Research shows that bicycle helmets prevent 88% of riders' brain injuries and 66% of all fatalities can be avoided with the proper use of helmets.² Many states have passed legislation requiring the use of bicycle helmets. As of July

1, 1996, all bicycle riders eight years of age and younger are required to wear a helmet in Rhode Island. Furthermore, legislation in combination with an educational program is more effective than legislation alone in promoting the use of bicycle helmets.³

To boost the effectiveness of our legislation, we decided to educate children about wearing helmets. As a health-based group project at Brown University School of Medicine, we wanted to encourage the use of helmets. By establishing working relationships with different agencies and institutions around the Providence area, we mobilized a community coalition to support our efforts to convey a safety message to children and families.

PROBLEM IDENTIFICATION

We searched for an area in Providence which had a low bicycle helmet utilization rate and which had a community center where our intervention could be deployed. After reviewing the Providence Recreation Department's evening barbecue schedule and consulting with the RI Department of Health, we targeted the Fox Point community. Low levels of bicycle helmet use among children was indeed a problem in that community. Over a six day period, we made 70 observations (Table 1). Only 5.7% all children

Abbreviations Used:

NHTSA National Highway Traffic Safety Administration

observed wore helmets.

METHODS AND MATERIALS

We adopted three strategies from a Seattle campaign as the backbone of our project: 1) Raising awareness, 2) Lowering the price of helmets, and 3) Inducing children to wear them. The Seattle campaign, held during 1987-1989, identified three major obstacles to helmet use. First, people do not understand their proper use and importance. Secondly, helmets are often expensive, selling for \$40-\$60 in specialty shops. Third, children often are reluctant to use helmets because many of their peers do not use them, and people who use helmets might appear different or "nerdy." The Seattle campaign addressed each of these obstacles and increased helmet usage among school-aged children from 5% to 16%, compared to a rise of only 1% to 3% in a control community.⁴

Our project addressed each of these obstacles during a cookout at the Fox Point Boys and Girls Club (part of the Providence Recreation Department's schedule of weekly summer cookouts). The components of our Bicycle Helmet Safety Program will be presented in terms of the obstacles they were intended to address.

1. Raising awareness

The first obstacle was providing information to the community concerning the importance and proper use of bicycle helmets. We addressed this obstacle with a variety of sources. First, at the cookout we developed and distributed a brochure (duplicated by Citizens Bank) to children and parents. The brochure discussed:

Table 1. Observations of Helmet Use

Gender	Age	with helmet	without helmet
Female	under 8	2	8
	between 8 and 12	0	9
	between 13 and 18	0	4
Male	under 8	2	17
	between 8 and 12	0	9
	between 13 and 18	0	19

1. Why helmets are important
2. Bicycle helmet laws in various states
3. How to wear a helmet properly
4. Three tests to ensure a helmet fits correctly
5. Other bicycle safety tips
6. What to look for in purchasing a helmet
7. Where bicycle helmets may be purchased

Secondly, we contacted the National Highway Traffic Safety Administration (NHTSA) and the Rhode Island Department of Health through the Providence Safe Communities Partnership. Both NHTSA and the Department of Health gave us additional brochures and posters to distribute at the cookout. Lastly, WJAR/Channel 10 covered the event, and a segment appeared on the evening news the following day.

2. Lowering the price of helmets

The second obstacle was the often prohibitive purchase price of helmets. We approached this problem in three ways. First, we asked the Kiwanis International Club to attend the event and sell helmets. They agreed to sell helmets at cost, for \$10. Secondly, we asked two local bicycle stores, Providence Cycle and East Providence Cycle, to sell helmets at a discount to people who attended our event. To facilitate this, our brochures included advertisements which served as 20% discount coupons for each of the bicycle stores. The brochures stated that people should bring them to the store to receive the discount. Lastly, with funding from Memorial Hospital of Rhode Island, we purchased 10 helmets from the Kiwanis Club and raffled them to children at the event. (We numbered each brochure to select the winners.)

3. Inducing children to wear helmets

The third obstacle was the perception of helmets as "nerdy." We had two approaches. First, through funding from Memorial Hospital of Rhode Island, we hired the Maximum Velocity bicycle stunt team to perform two shows at the cookout. Maximum Velocity's riders, some of whom appeared in ESPN's X Games last summer in Rhode Island, performed

bicycle tricks to music while their captain explained the importance of helmets and other protective gear. He stressed that the use of helmets extended beyond doing tricks to everyday riding. Secondly, through the RI Brain Injury Foundation, we invited an 18 year old female from Rhode Island who suffered head injuries while riding a bicycle to speak to the attendees. She told the story of her injury - and how a helmet could have prevented many of the sequelae she experiences each day.

Bicycle helmets have been proven to prevent both injury and fatalities.

Research shows that bicycle helmets prevent 88% of riders' brain injuries and 66% of all fatalities ...



RESULTS AND DISCUSSION

1. Raising awareness

As we analyze each segment of our program and its success, there were many positive aspects as well as lessons to be learned. First, we wanted to reach an underserved population and address children in an environment where their parents would also be present, since it is often the parents who can best comprehend the information and will purchase helmets for their children. We estimated that approximately 300-350 people would attend the Fox Point cookout; however, the attendance was approximately 200 people, with two-thirds of them children. Therefore, we did not directly reach as many people as we hoped; more importantly, we did not reach as many parents with their children as we had intended. One explanation for decreased attendance was that the original event was rained out and the new date was scheduled 5 days before it occurred.

The involvement of the local media and the segment which aired the following evening spread our message to a larger audience than the actual attendees. Additionally, the media may have relayed the message to children in

attendance that this is a "serious" matter, reinforcing our message.

The brochures and posters that we distributed were received primarily by children. In particular, our brochures with raffle numbers on top were a "hot" item among the children because they could "win" a prize if they collected enough brochures with numbers on them. As a result, our brochures were not distributed properly; and much of the information and discount coupons did not end up in the hands of people who could use the information, such as parents and grandparents. For future projects, the children should have to earn an opportunity to win a helmet by answering bicycle safety questions correctly or completing a bicycle rodeo event successfully. This way, the helmets would represent something earned, and perceived to have more value, rather than a free prize. We thought by putting numbers on the brochures that more children would pick up brochures, and hopefully more of the brochures would make it back to their homes. However, after the raffle numbers were called, many of the brochures made their way to the sidewalks and trash containers.

2. Lowering the price of helmets

Our decision to sell helmets at the event was a good one in design, but not so effective in practice. The Kiwanis Club sold approximately 6 helmets during the event, almost entirely to parents and grandparents. We had hoped that the the cost price of \$10 would have attracted more buyers. It appeared that many more people were interested in buying helmets than actually bought them. When asked, most of these people (and children) said that they did not bring \$10 with them that evening. In our advertisement of the event, we stated that helmets would be on sale for \$10, but due to the first rain-out, people may not have realized that the bicycle safety program would be held at the rescheduled time, or did not see the new flyers publicizing the rescheduled date. For future projects, better publicity of the sale of helmets might spur more people to bring money and buy helmets. Also, one week after the event, both bicycle shops were contacted to see whether any of the coupons were re-

deemed. Neither of the shops reported coupon redemptions.

3. Inducing children to wear helmets

The most effective part of our program was our attempt to change the perception of helmets as "nerdy." Maximum Velocity's two stunt shows appeared to be the highlight of the event. Most children in the audience had eyes glued to the action. When asked, many of the children stated that they would be more willing to wear helmets in the future. The 18 year old female's "victim" speech, which took place between the two stunt shows, was emotional, heartfelt and appeared effective. At the beginning of the speech nearly all of the children were actively listening to her explain her accident. As her talk continued, some children lost interest while others were captivated and brought to tears. As children lost interest, she became discouraged and actually ended her speech prematurely. In the future, we would suggest to anyone addressing children that it is crucial to keep them involved, not lecturing to them, and keep what you have to say short and to the point, recognizing that their attention span is shorter than that of adults.

CONCLUSIONS

The small number of parents at the event probably reduced the effectiveness of our campaign. Despite our attempts at making helmets more affordable, few were purchased. In addition, postponement of the event due to rain had an adverse effect. Perhaps if the rain had not forced us to reschedule, or if other events at the cookout had drawn more parents, our efforts might have been more successful.

Although the helmet raffle excited the children, their motivations for wanting one strayed from our intentions. Many children wanted to win one, to sell to someone else. Some simply wanted to win something. Perhaps an activity that included the children in a knowledge test where the helmets were awarded as prizes would have been a better strategy. This way, the helmets would feel like something earned (and thus perceived to have more value), not a prize.

Even given the advantages of Fox

Point in meeting our goals, there were some drawbacks as well. Our selection of community sites (chosen from the weekly Providence Recreation Department cookout schedule) was limited. The Fox Point community is small, spanning roughly one square mile. Consequently, we could not reach as many preadolescent children as we hoped.

Despite these limitations, our project did begin to change the perception of helmets among the children at the event. Perhaps this can be viewed as the most important accomplishment, because without any desire to wear helmets, information dissemination, price reduction, or even legislation can only do so much to get a child to pick up a helmet.

Another accomplishment was the success of utilizing a community coalition to pool resources and provide a needed service to the community. Tremendous resources were available to us through the coordination among different community agencies. Changing popular impressions, such as how children think of helmets, takes not only a multidimensional approach, as we did here, but a prolonged effort. The successful Seattle campaign took three years. Hopefully, the children of the Fox Point community and other Rhode Island communities will be exposed to more influences that promote bicycle helmet use such that wearing a helmet will not be considered different but the norm.

To date, we have not performed follow-up studies to examine how effective our program was in changing the utilization of bicycle helmets in the Fox Point community, primarily because of the time constraints of our project. However, we maintain that even if but one child has changed his/her perception of wearing a helmet or now consistently wears one, we have accomplished what we set out to do. Not only did we reach out to the Fox Point community directly, but indirectly to all of Southeastern New England via the media. Hopefully, children and their parents watching the news coverage were impressed by the program and have changed their opinions about bicycle helmets.

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The Effect of Socioeconomic Status, Ethnicity, and Sex on Subjective Life Expectancy among Adolescent Rhode Islanders

Shoshana Landow, BA, Elisa Rhew, AB, Linda Shiue, AB, and Paul Simmons, MA

Socioeconomic status (SES) has been shown to correlate with actual life expectancy.¹ Subjective life expectancy (SLE), an individual's estimate of his or her own life span, and the factors that influence it, have not been as well-studied. Researchers have explored the disparity between subjects' perceived and actual life expectancies while trying to relate these inconsistencies to certain characteristics. Joubert found that women who scored highest on a "happiness" scale had a longer SLE than those who scored lower.² SLE has also been related to psychological and experiential factors, such as "death anxiety" and the average life span of deceased relatives.^{3,4}

Tolor et al explored "experiential variables and the projected life span." Male subjects overestimated their life expectancy more than did female subjects. Additionally, subjects who experienced the death of a spouse, close relative, or friend tended to underestimate their life expectancy.⁵ Hammerhesh et al found a discrepancy between the actual life expectancy and the reported SLE in subjects who engage in certain adverse health behaviors: people understand that smoking decreases their life span, but not that a sedentary lifestyle does.⁶ None of these studies explores what factors influence adolescents' subjective life expectancy and projected cause of death.

According to Eric Erikson, teenagers must recognize that death is irreversible by developing their own coping mechanisms. Indeed, humans cannot grasp the concept of permanent death until age 11 or 12, when we advance beyond the Piagetian stage of concrete operations to that of logical thought.⁷ Ideally, they will develop an optimistic attitude toward their future as well as toward the meaning of life and death.

But this is not always the case. Gordon notes that American society does little to help adolescents in this endeavor: adolescents view popular depictions of death as "excessively violent, macabre, distant, or unnaturally beautiful."⁸ Koocher et al found that, far from thinking that they are immortal, normal adolescents have death anxiety.⁹ Gordon suggests that risky behavior among teenagers, such as car racing or excessive use of drugs and alcohol, reflects a counterphobic reaction to a disturbing awareness of their mortality.

So, do adolescents think they are immortal, or do some of them think they will die young? Do those of lower SES have a less optimistic view of their life? Adolescents' perception of their own life expectancy is the tool we choose to explore this optimism. Our study focuses on whether adolescents of higher socioeconomic status project more optimistic life expectancies, as well as more benign causes of death. Tolor's findings, that his male subjects had longer SLE than the females,⁵ prompt us also to investigate a relationship between sex and SLE. Last, we hypothesize that ethnicity affects SLE, with Whites having more optimism than Non-whites.

MATERIALS AND METHODS

In February 1997, we administered a one-page questionnaire to adolescents in Providence and Cranston,

Abbreviations Used:

SES	socioeconomic status
SLE	subjective life expectancy

Rhode Island. The survey probed demographic information, parental information, and future expectations, including, "How long do you expect to live?" and, "What do you expect your cause of death to be?" In total, we analyzed 172 completed surveys

Table 1
Subjective Life Expectancy (SLE)

<u>SLE (years)</u>	<u>Number of subjects</u>
25-69	20 (11.6%)
70-85	42 (24.4%)
86-123	82 (47.7%)
Unknown*	28 (16.3%)
Mean	84.0
S.D.	18.1
Median	88.0
Mode	100

* subjects left this question blank

Table 2
Subjective Cause of Death

<u>Causes</u>	<u>Number of subjects</u>
Natural	124 (72.1%)
Old Age	111 (64.5%)
Disease	13 (7.6%)
Non-natural	30 (17.4%)
Accident	6 (3.5%)
Violence	12 (7.0%)
Other	12 (7.0%)
Unknown*	18 (10.5%)

* subjects left this question blank

from adolescents aged 13 through 18. No one site represented more than 50% of responses.

Ethnicity was reported as one of 5 categories: Caucasian/white, African-American/black, Asian/Pacific Islander, Hispanic/Latino, and Multiracial. We divided the subjects into 2 groups: White and Non-white. SES was determined using parental information on educational level and occupation with a modified version of the Hollingshead "two-factor index of social position."¹⁰

Subjective Life Expectancy was obtained as continuous data with responses ranging from 25 years to infinity. We narrowed this range, dividing it into three groups - those with SLEs from 25 to 69 years, 70 to 85 years, and 86 to 123 years. The middle group (70 - 85) encompasses the subjects' actual life expectancies.¹¹

Subjects chose among five modes of dying: old age, disease, accident, violence, and other. We grouped these causes into "natural" (including old-age and disease) and "non-natural."

STATISTICAL METHODS

After defining our variables, we carried out several tests of significance. Where 2x2 tables could be constructed, we estimated odds ratios and 95% confidence intervals. In other cases, we calculated Chi-square values as well as Pearson's *r*. The variables SES and SLE were analyzed both as continuous and categorical. To consider possible confounding by several factors, mathematical modeling with multiple regression was used.

RESULTS

In this cross-sectional study, the three major independent variables are SES, ethnicity, and sex. The two dependent variables are subjective life expectancy (SLE) and subjective cause of death.

The respondents ranged in age from 13 to 18 years, with a mean of 15.2 (S.D. 1.2). One hundred and seven respondents were White, 63 were Non-white. There were 52 males and 83 females. A large number of subjects, 21.5%, did not specify their sex.

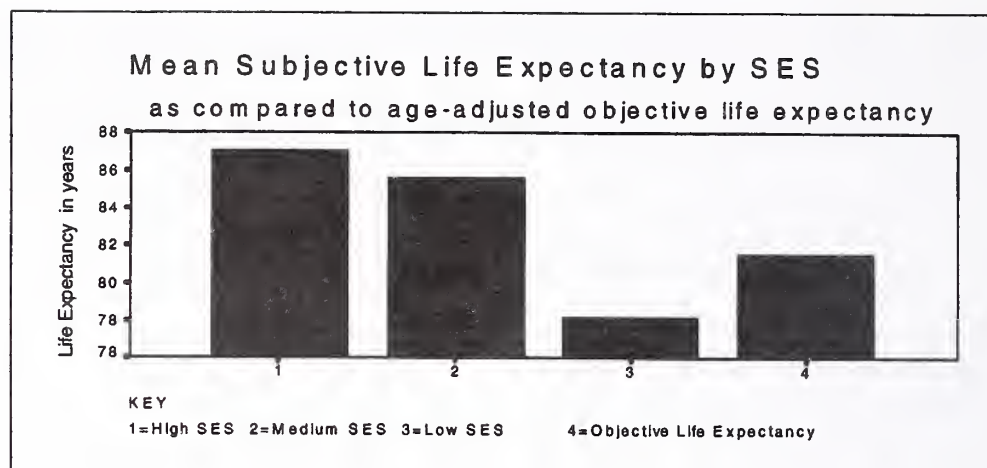


Figure 1.

SES scores ranged from 11-47 with a mean of 24.7 (S.D. 11.8): 30.2% of the subjects had a low SES, 20.9% had a medium SES, 39.5% had a high SES, and 9.3%, who did not provide adequate data to calculate an SES score, were counted as missing data.

The respondents reported a mean subjective life expectancy of 84 years (S.D. 18.1) (see Table 1). Forty-seven percent, the largest of the three groups, predicted a life expectancy that fell between 86 and 123 years. One quarter of the subjects fell within the range that encompasses the objective life expectancy for persons of their age group (70-85). The 25- to 69-year expectancy was the smallest group, with only 11.6% of the subjects. 16.3% left this question blank.

Most of the students estimate their life expectancy to be greater than 86 years of age. However, a significantly larger proportion in the higher SES group than in the lower SES group expect to live beyond 86. Similarly, a larger proportion of the lower SES group expects to live less than 70 years of age (Chi-square=10.4, $p=0.03$). The Pearson's *r* was -0.28 ($p<0.05$) indicating a slight negative correlation between high SES and low life expectancy. ANOVA analysis was also done using SLE as a continuous variable. This confirms the differences among the three SES groups ($F=3.1$, $p<0.05$). This association remains significant even when controlling for potential confounders. With subjective cause of death (natural vs non-natural) and sex entered into a multiple regression model, the association be-

tween SES and subjective life expectancy remains significant ($T=-2.066$, sig. $T=0.04$). A significant difference also exists between males and females when reporting life expectancies. The difference between Whites and Non-whites is just beyond the range of significance ($X^2=4.2$, $p=0.12$) with respect to SLE.

When compared to non-natural causes of death, natural causes are expected by more than four times the number of subjects, with the majority of respondents predicting that they will die of old age (see Table 2). The relationships between subjective cause of death and SES show no statistical significance, nor do those between subjective cause of death and the other exposures, ethnicity and sex.

Figure I compares mean subjective life expectancy by SES category to objective life expectancy by age. The mean objective life expectancy was derived from age-adjusted data obtained from the U.S Census Bureau,¹¹ and was a weighted average for our study population. The high and medium SES categories have a mean greater than the weighted mean of the U.S. Census Bureau's life expectancy, while the low SES category has a lower mean.

DISCUSSION

Adolescents do not think that they are immortal. Overall, they have a high subjective life expectancy, regardless of sex, ethnicity, or SES. Our study demonstrates that adolescents of higher and middle SES levels report a mean life expectancy that is greater than the weighted mean of age-adjusted Census Bureau life expectancy, while those

of lower SES levels report a lower mean SLE.

The mode for SLE of all subjects was 100 years of age (21 subjects). Since few humans live to be 100, this high mode reflects the fact that although adolescents do incorporate the notion of mortality into their own life stories, they still have not fully aligned it with reality. Three possible explanations suggest themselves: First, these students are unrealistically optimistic because they do not fully understand their mortality; second, they are manifesting denial in response to death anxiety, or third, it may be something as simple as the attraction of a nice, round number. A substantial number of respondents (11.6%) did not answer this question. Several subjects who refused to fill out the third section of the survey annotated their missing answers with comments such as, "I don't want to think about that now," or "I'm not paranoid." As theorized by developmental psychologists, adolescents are at a juncture where logic and day-to-day reminders of their mortality in the form of aches and pains, illnesses, and even death of loved ones, are beginning to replace the notions of death impermanence and immortality. Not answering the questions may reflect the death anxiety that Koocher et al hypothesized in normal adolescents.⁹

Regardless of the reasons, this study demonstrates that adolescents are prone to over-estimating their life expectancies. If "unknown" responses are discarded, a majority of subjects thought they would live beyond age 85, which is the highest life expectancy for their age group (85.4 being the life expectancy for U.S. white females aged 13-18.)

There are, however, significant differences in the way students from the different SES predict their own life expectancies. These differences maintain significance when adjusted for confounding by subjective cause of death and sex. A greater proportion of subjects in lower SES groups expect earlier death than subjects in the higher SES groups. This difference is borderline-significant when examining SLE in the context of ethnicity. SLE varies

significantly between males and females, with a larger proportion of males projecting earlier deaths than females.

Our study demonstrates that adolescents of higher and middle SES levels report a mean life expectancy that is greater than the weighted mean of age-adjusted Census Bureau life expectancy, while those of lower SES levels report a lower mean life expectancy.



Do these differences reflect the adolescents' knowledge of actual correlations between life expectancy and SES? Do they reflect their internalization of popular culture? Erikson suggests that the life-cycle stages of adolescents among differing ethnic or socio-economic groups may be experienced differently - specifically, that children from minority and low-income backgrounds may experience more difficulties in achieving positive developmental outcomes because they are more likely to encounter discrimi-

nation or other barriers. This increasing difficulty in achieving positive developmental outcomes may play out as a sense of lack of control as well as a less optimistic outlook concerning one's life, health, and longevity.

Our study did not demonstrate an association between projected nature of death and any of the three variables, sex, ethnicity, or SES. A large majority of the respondents report that they are likely to die from natural causes, with a majority of those choosing "old age." It is possible, of course, that a majority of people of any age would predict benign causes of death.

LIMITATIONS

In general, cross-sectional studies cannot establish causality between "exposure" and "outcome" since they are assessed at the same point in time. In this study, however, common sense suggests that SLE could not cause an adolescent's SES. Thus, it is likely that the association between the three variables - SES, sex, and ethnicity - and SLE may indeed be causal.

Misclassification of SES is possible in this study. Using a modified version of the widely-accepted Hollingshead "Two-factor index of social position,"¹⁰ we instructed students to leave blank the answers they did not know. This creates the possibility for systematic recall bias if, for example, students whose parents have prestigious occupations (and thus a higher SES) are more likely to know what their parents do. Alternatively, if adolescents

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in one particular SES are less likely to know their parents' occupations, they might mis-report unwittingly. Indeed, if students who should have been in the lower SES systematically inflated their ranking, this would have underestimated the true association between the "exposure" and "outcome."

Misclassification of subjects' "exposures" may also have led to bias. The division of "Ethnicity" into White and Non-white lumped together Hispanics and Asians. If those different ethnic groups have, in fact, very different attitudes towards mortality, this would only increase the association found in our study.

Confounding bias was addressed during data analysis with multiple regression modeling, which showed that the correlation between SES and SLE is still significant even after adjusting for subjective cause of death, and sex.

CONCLUSION

Our study shows a statistically significant correlation between adolescents' subjective life expectancy and their SES. Further, females have a longer SLE than males, and Whites may have a longer SLE than Non-whites. This can be seen as a reflection of the optimism or pessimism with which these groups view their lives.

This is in agreement with Jessor et al who established that as SES increased, so did adolescents' perceived access to future opportunity. What is a sense of future opportunity if not a sense of optimism? Jessor et al showed

a consistent, positive relation between perceived life chances and health behavior index, indicating that the greater the perception of access to future opportunity, the greater the involvement in positive health behavior. Further, they showed that SES was a significant and important factor in both the perception of life chances and positive health behavior.¹²

The question that remains to be studied more fully is whether SLE alone could be used as a predictor of healthy behavior. Do adolescents' beliefs about their own mortality affect behaviors such as health maintenance and risk-taking? If yes, then a patient's SLE can be used by clinicians to get a stronger idea of that patient's view about his or her own health. This is of importance to us as clinicians in that it will increase our awareness of how patients' beliefs may affect their health behavior. It can help to shape our approach to patients, giving us a way to address beliefs that may lie behind destructive health behaviors. This will improve health care delivery and effectiveness.

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Changing the Role of the French Physician:

Cost Containment in the French Health Care System

Jonathan D. Agnew, AB

Last March, the 8:00 p.m. news in France broadcast a series of images that said more about current conflicts between doctors and the state than any government report or newspaper column. Several hundred medical interns staged a strike on the steps of the National Assembly in Paris to protest government reforms. These reforms, designed to reduce the overall cost of health care, included legislation that would impose stiff financial penalties for doctors who overprescribed certain medications. Camera crews arrived in time to film riot police dragging the young doctors-to-be into police vans. The future of medicine was, literally, in the hands of the state.

If the image of clashes between riot police and doctors in France seems foreign to American physicians, the economic constraints facing their French colleagues appear hauntingly familiar. In a system where health policy is increasingly determined by concerns over costs, French doctors find themselves in the center of the health care debate. This paper explores the changing role of the French physician by discussing the structure of the French health care system, the reasons behind the dramatic increase in health care costs, and finally, the similarities in the French and American systems.

STRUCTURE OF THE FRENCH HEALTH CARE SYSTEM

The French health care system is most aptly described as a system of national health insurance (NHI). The system functions under the larger structure of the national Social Security Organization (*la sécurité sociale*), which also includes programs for family welfare allocations and pension funds. Rather than control health care directly by employing all doctors and/or owning all hospitals, the French govern-

ment oversees a national health insurance system that reimburses doctors and hospitals in both the public and private sectors. This hybrid public/private system points to the reality that health care delivery is more the result of historical accident and the pressures of special interests than any sort of advance planning.

Today, nearly 90% of NHI revenue comes from employer and employee contributions, for whom participation in the program is obligatory. Employers usually pay 70% of the social security tax for each employee, while the employee picks up the remaining 30%. Approximately 10% of the revenue comes from state subsidies.¹ Remarkably, this system provides comprehensive health insurance to 98% of the population at a cost of only 9.4% of the Gross National Product (GNP)—a sharp contrast to the American system which does not guarantee coverage to the entire population but consumes nearly 15% of the GNP.

THE HEALTH CARE COST INCREASE

Hardly an issue of France's daily *Le Monde* is published without a reference to the growing cost of health care. The social security deficit, which reached an all time high of \$14.8 billion in 1995, continues to grow. Nearly two-thirds of this deficit is due to the NHI debt of \$9 billion.² This fiscal crisis has spurred political leaders and administrative bodies to introduce numerous cost-control reforms. Groups of doctors, nurses, workers' unions, and hospital administrators have often resisted these efforts, claiming that any rationing or decrease in the quality of medical care would only worsen an already difficult situation.³

Abbreviations Used:

DRG	diagnosis related groups
NHI	National Health Insurance

Like most industrialized countries, France has seen a rapid increase in its health care costs over the past 25 years. The percentage of the GNP devoted to health care spending has been increasing faster than both inflation and population growth. In 24 years, medical consumption increased more than 550% while the population increased only 20%.⁴ This rapid increase is due in large part to:

1) *A general economic crisis in the late 1970s*

A general economic recession in the early 1970s, initiated in part by the oil crisis, ended the period of growth following World War II. An inflation rate of 14% and an annual real growth rate of less than 1% put the government under severe spending constraints. Nonetheless, health care spending continued to increase as a percentage of the GNP and the deficit began to grow. Because Social Security relies heavily on the contributions of salaried professionals and their employers, rising unemployment translates into fewer contributing individuals—while the number of individuals requiring medical care remains the same. The government is then forced to increase social security taxes to pay for the difference in cost. The increased taxes in turn provide a disincentive for employers to hire new people since health care is such a significant expense. If economic conditions remain unfavorable, unemployment rises and the cycle repeats itself: social security funds go down, taxes increase, and unemployment stays high. This pattern continues today, where the unemployment

rate in France is nearly 14%, and employers remain wary of hiring new employees for fear of the increased costs they would represent.⁵

2) *An aging population*

Like most developed countries, France has completed both the demographic and epidemiologic transitions. The percentage of the population above the retirement age is increasing, and causes of morbidity and mortality are generally associated with chronic conditions like heart disease and cancer.

3) *Uncontrolled growth of hospitals*

Until 1984, French hospitals were reimbursed on a *per diem* basis. Without any incentive to cut costs, hospitals' budgets grew at an alarming rate. The implementation of global budgets after 1984, followed more recently by importation of the American DRG (diagnosis related groups) system, will likely contain hospital costs.

4) *Increased physician activity*

Along with hospitals, doctors are responsible for most medical costs in France. They diagnose the illnesses, prescribe the medications, and order the tests. Any increase in their activity will increase expenditures: the 45% increase in medical services over the past ten years is correlated to the 42% increase in the number of practicing doctors.⁶ Physician incomes have increased steadily since 1970. In 1970, the average doctor earned \$26,600; by 1981, s/he earned \$46,800. However, relative to the average French income, doctors' wages actually decreased: in 1970, doctors made almost 5 times that of the average French worker. By 1981, this had dropped to 3.3 times the average salary.

5) *Few and ineffective restraints on patient activity*

Physicians cannot be blamed entirely for the cost increase, because along with near-universal coverage by 1974 came the growing public perception of health care as a right, not a privilege. In political terms, this means that reducing NHI benefits or limiting ac-

cess to care is political suicide. Today, a Frenchman could conceivably see five doctors in one day and get reimbursed for all the visits even if only one was necessary. The only limit on patient activity is the so-called *ticket modérateur*, or physician co-payment. Yet by 1995, fully one-third of the population had purchased private insurance to cover co-payment costs. The one barrier to access is thus removed for a significant portion of the population.⁷

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CUTTING COSTS AND THE CHANGING ROLE OF THE DOCTOR

The relationship between the doctors and the state is probably one of the most defining characteristics of the French health care system. In no country have the latent controversies between state control, free enterprise, and the practice of medicine come together in such a dynamic way.

French doctors have traditionally practiced what they call *la médecine libérale*—literally “liberal medicine”. Liberal does not refer to the political left, but to the “nineteenth-century European sense of laissez faire, individualism, and free choice.”⁸ Liberal medicine in France, therefore, refers to the practice of medicine free from the direct control of the state. For doctors, this encompasses four basic principles:

- 1) Free choice of doctor by the patient complemented by physician and patient agreement on fees;
- 2) Freedom of prescription by the doctor;
- 3) Direct payment by the patient for services rendered;
- 4) Guarantee of professional confidentiality.

When French doctors oppose efforts to reform the health care system, it is usually on the grounds that it violates the principles of *la médecine libérale*. And yet the first of these principles was eliminated several decades ago with the advent of NHI: French doctors and their patients no longer determine fees independently. Instead, Social Security determines reimbursement rates. Regulating physician income is the first of two ways that the social security administration and the state minimize the cost of doctors to the health care system. The second step has been to restrict the opportunities doctors have to practice medicine.

Regulating Doctors' Income

This is the most politically charged issue in the French system. The determination of the social security reimbursement rates is a continual struggle between and a reflection of the strife between doctors and the state. Because physicians have lost the right to set their own fees, physicians must accept decreasing reimbursement rates. Until recently, many have attempted to increase their income by changing their reimbursement status. Social security offers physicians two reimbursement “plans.” The first, “Sector 1,” allows doctors to charge their patients only the rates established by the social security fee schedule. In return, the individual physician pays reduced income taxes. Under the second plan (Sector 2), doctors may charge above the fee schedule but must pay higher taxes in exchange for this right. Feeling that the potential gains from charging fees above the fee schedule would be greater than the costs incurred from an increased income tax, a total of 105,164 doctors left Sector 1 for Sector 2 during 1987-89. In response, Prime Minister Chirac froze access to sector 2 in 1989, limiting it to 40% of the total medical corps. The protests of medical unions were futile.

The effect of imposed fee schedules on the medical profession has been noticeable. In 1983, there was a social security surplus of 11.3 FF billion.⁹ Apparently this was not enough to counteract other pressures to increase

costs, since a deficit of 2.5FF billion returned in 1989 and has continued growing ever since. The social security administration found that keeping reimbursement rate increases below the rate of inflation did contain health care costs.

A further form of control was the establishment of "physician profiles" in 1971. The procedures performed by physicians are kept on record. Any physician with irregular practice patterns is, in theory, alerted and/or sanctioned. However, criteria on how much medicine is too much have not yet been agreed upon, and it remains difficult to control doctors in this manner.¹⁰ The development of more sophisticated monitoring procedures (such as computerization of the profiles) will eventually allow social security to more effectively regulate physician costs.

Restricting the opportunity to practice medicine

The French state has regulated the number of students allowed to enter medical school and limited the number of medical school graduates allowed to specialize. The former represents reversal of health policy in 1965, when demographic studies predicted a shortage of between 7,000 and 11,500 physicians. Since the 1977 peak of 9,186 students, the number of medical school graduates has steadily decreased. In 1986, only 4,750 students graduated.¹¹ The reason has been the institution of the *numerus clausus*, or medical student quota. By law, all students who have passed the *baccalaureat* (equivalent to a high school diploma) have the right to attend the first year of medical school. However, difficult exams at the end of the first year restrict the number of students continuing on to the second year.

Given that social security reimbursement for specialists is roughly 35% higher than that of generalists, it is in the interest of the state to limit the number of specialists. This is especially important in France where the general practitioner does not function as a gatekeeper and specialists proliferate. Like second year medical school

admissions, selection of medical students allowed to specialize is done by a competitive examination (the INTERNAT). Each year, the government determines how many doctors will specialize. The top performers on the INTERNAT corresponding to this number have the right to choose their specialty.

CONCLUSION

The striking medical interns, carried off by the riot police, did not convince the government to change its policies. Although the striking interns managed to delay the reforms for seven years, such action only postpones the inevitable. By restricting income, the right to enter the medical profession, and the opportunities to specialize, the French government has already exerted remarkable influence on the practice of medicine, and it is unlikely that this will change in the near future.

How is all of this to be understood from the perspective of an American physician? Despite differences in culture and political orientation, there are health care similarities between France and the United States. Both have watched health care costs escalate, and both are struggling to contain that escalation. But more importantly, both have chosen to regulate doctors as a means of reducing costs. Americans quick to criticize France's strong interventionist state as too harsh on doctors need only look at the nearest HMO to see a similar pattern of regulation. In reality, the payer determines policy. In France, it is the state that pays, while in the U.S., the private sector pays most of the bill. The true difference is not so much the effect this has on doctors and their practice patterns (since in each country doctors have lost a significant amount of autonomy), but on the delivery of health care to the population. The French state has an obligation to ensure everyone access to health care, regardless of ability to pay. That the French meet this obligation and spend only 9.4% of the GNP doing so is worthy of consideration by the American medical community.

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Sick Call in Pediatric Residency Programs: The Chief Resident Perspective

Franz E. Babl, MD, MPH, Barbara Ziogas, MD, Carl Orkin, MD, and Edwin L. Zalneraitis, MD

Like any other employee or trainee, a resident physician can be absent from work – either because of illness or a non-medical emergency. Long working hours, sleep-deprivation, insecurity about competence, high patient turnover, a competitive and intimidating environment, constant exposure to illness, disability and death¹⁻⁵ – all increase the risk of absence, as do stresses outside work (geographic relocation, loss of support systems, limited free time, problems with spouses and significant others, debts from medical school, and depression.)^{1,4,6-10} Pregnant residents face risk for preterm labor, preterm delivery, low birth weight infants, pregnancy induced hypertension, and placental abruption¹¹⁻¹⁸

Absent trainees must be replaced in a way to ensure the functioning of the clinical services. Often the chief resident or program director must find another resident to cover for the missing trainee, either by *ad hoc* scheduling or by a formal pre-established sick call policy.

Despite the prevalence and difficulty of resident physician absence, a review of the English literature yielded only one pediatric report about a single program's sick call system.¹⁹ An investigation of sick call systems to replace absent residents is now timely: the revised Residency Review Committee (RRC) for Pediatrics mandates a sick call system or alternate plan for absent residents.²⁰

This study investigated sick call systems in 15 pediatric residency programs in one regional organization. A survey, done prior to the implementation of the new RRC requirements, identified the sick call systems used, the problems encountered and possible

solutions for those problems.

METHODS

In January and February 1995 questionnaires were sent to the chief residents of all 15 member pediatric residency programs of the NEPPD, including all the pediatric residency training programs in New England and the program in Albany, New York. Programs with more than one chief resident were asked for a consensus opinion. (The data were amended following presentation at the Northeast Pediatric Program Directors and Chief Residents Annual Spring Meeting in Farmington, CT, on April 5, 1995.)

Closed and open-ended questions probed: the triggering events that would initiate the sick call system, the participants in the system, the call pay-back provisions, the scheduling systems, the use of paid call, the use of nurse practitioners and physician assistants, and the satisfaction (resident, faculty and chief resident) with the system. The chief residents were asked to describe problems or abuse in their system, and any recent or future changes. The results were stratified into large (more than 30 residents) and small (fewer than 30 residents) programs.

RESULTS

The 15 programs had a total of 539 pediatric residents, including those combining internal medicine-pediatric residents. The average number of residents per program was 35.9 with a range of 15 to 82. Six programs had fewer than 30 residents; 9 had more than 30.

All 9 large programs had a des-

Abbreviations Used:

NEPPD	New England Pediatric Program Directors
RRC	Residency Review Committee

ignated resident on sick call, in case of resident absence, at all times; only one of the 6 small programs did. Sick call schedules were organized in a variety of ways: scattered calls throughout the year, scattered calls during electives, block assignments to sick call for 1-2 weeks, a 1-month block of sick call every other day, and a combination of scattered calls throughout the year plus a block of every third night sick call availability. Two programs scheduled additional sick call assignments in case of residents' long-term illnesses.

Illness was the key trigger, but only two programs used specific criteria, such as fever at or above 100.5F or symptoms of orthostatic hypotension.

In addition to acute illness, all programs considered family emergencies, such as illness of a child, a valid reason. Seven of the 15 programs considered child care problems as valid. Two other circumstances reported as legitimate reasons for absence were jury duty and exposure to *Varicella zoster*. The chief residents reported a long list of other reasons, not included in their sick call policy, that residents cited when requesting sick leave; e.g., car stolen, marital discord, funerals of relatives or friends, forgetting a call assignment, precall insomnia, daughter in a spelling bee, being radioactive due to thyroid tumor irradiation, and eloping to Paris.

First year (PL-1) residents participated in the sick call coverage in 5 of the 6 small programs, but in only 3 of

the 9 large programs. The chief residents themselves, both those in the third (PL-3) and fourth (PL-4) years of training, were required to provide some sick call coverage in 5 of the small programs, but in only 1 of the large programs.

Only 4 programs paid residents for providing coverage. One program paid \$200 for every sick call lasting beyond 4 hours; a second paid \$35 per hour only after the regular sick call system was exhausted; a third paid \$40 per hour for every sick call coverage beyond the first call missed by a resident related to a single illness or emergency; a fourth paid \$50 per hour to a resident if more than two residents were out sick at the same time. None of the programs used extended care providers for sick call coverage.

If a resident missed more than one consecutive call, sick call plans employed: continued coverage by the sick call person, sick call initially plus paid call for the additional absence, the assigned sick call resident plus overall schedule changes, case by case decisions or use of a long term illness resident coverage plan.

When residents used the sick call system, whether through an pre-established or *ad hoc* system, they had to compensate ("payback") for their coverage by taking an additional call at a later time in 9 of the programs (5 of the 6 small programs, 1 of the 9 large programs). With one exception the "payback" was to the resident who had covered for the resident unable to be on duty.

Resident complaints about the sick call, as perceived by the chief resident, included the additional call burden (4 programs), abuse by colleagues (4 programs), the need to payback or lack of payback for sick call coverage (3 programs), and not having a sick call system (1 program). Faculty complaints, reported in only 3 programs, involved residents being pulled unexpectedly off elective rotations as a result of scheduling changes.

The chief residents in all programs

considered sick call a problem. Chief residents in the small programs complained about difficulty in finding a resident to provide coverage, and having to cover for an absent resident themselves. In the large programs, problems included: scheduling difficulties for both sick call and payback calls, discomfort in asking residents to cover on days when their only assignment was sick call coverage, sick call residents being unavailable or uncontactable on scheduled days, the need to assess a resident's health, evaluating non-illness reasons for sick call requests, the frequent users or abusers of the sick call system, and residents who reported being too sick to work with a low severity of illness perceived by the chief resident. Programs with a system of sick call coverage done in blocks reported that the residents assigned to sick call could have excessive number and duration of clinical assignments during their blocks on sick call. In 2 programs, the chief residents described problems with sick call as the worst part of chief residency.

None of the chief residents of the small programs felt that abuse of the sick call by their residents was a problem (as opposed to residents in 4 of the larger programs). Three of the four programs reporting significant abuse had a call payback system in place.

None of the small programs changed their sick call system in the past three years. However, two thirds of the large programs changed their system, often repeatedly. Changes included: changing to a payback system (3 programs), the bundling of sick call into blocks or spreading the calls out instead of a block call system, establishment of a daytime sick call resident and requiring the sick call resident to take sick call in the hospital. Two of the small programs planned to introduce a sick call system within the next year. Two of the large programs planned to include PL-1 residents and spread out sick calls over the full three years of residency.

DISCUSSION

Few reports discuss sick or absent residents. A self-reported, prospective study of 42 pediatric residents and fellows found an annual rate of 6.7 illnesses and an annual rate of absenteeism due to illness of 2.8 days per resident or fellow.²¹ A retrospective study in 134 pediatric and internal medicine¹⁹ residents yielded an absence rate of 1.1% of all scheduled work days, with first year residents having the highest absence rate. In that study, 20% of the residents reported a chronic medical condition. Klevin et al¹⁸ reported that 38% of female pediatricians had become pregnant during residency; 36% of these residents experienced complications; and in 40% of residents experiencing complications, the difficulties cost time from training.

In some situations, unexpectedly absent residents will have no impact on patient care or educational activities. At other times, the duties of the missing resident can easily be absorbed by other residents. Sometimes, however, the absence of a resident leaves a critical shortage in coverage, affecting patient care, the call schedules, education of fellow residents, personal time of other residents, and ultimately the educational climate of the program.

A sick call system avoids having residents work when they are ill, potentially endangering their own health and the health of their patients. A sick call system can help distribute the unexpected duties fairly. In a study of internal medicine and pediatric residents, 97% of residents supported the sick call system, and 90% felt that it helped to reduce stress.¹⁹

Most of the small programs surveyed did not have a formal sick call system in place, and coverage for an absent resident was organized on an *ad hoc* basis. Residents at all levels of training were included in sick call coverage for these programs, with payback expected in most. Without a sick call system, chief residents must either find a replacement on short notice or

take the call themselves. None of the small programs had problems with residents abusing sick call. From our data it is not possible to say whether these programs would be better off with a formal sick call system. Technically, it would be more difficult to schedule a sick call system in small programs; those chief residents might then confront a different set of administrative problems.

In contrast, all the large programs had sick call systems, most without PL-1 residents or chief residents participating. Most of the chief residents complained about administering sick call, abuse of sick call and neglect of sick call duties. Abuse of the system seemed the most common and difficult problem, perhaps due to larger numbers of residents reducing interpersonal responsibility, a greater sense of entitlement to be absent for a wider variety of reasons with a sick call system in place, or less of a sense of cooperation. Abuse of the sick call system by individual residents, whether true or perceived, can demoralize the program. It was hypothesized, prior to the survey, that "paybacks" would decrease abuse. Interestingly, however, 3 of the 4 programs reporting significant abuse had a call payback system, while of the 5 programs without a payback requirement, only 1 reported significant abuse.

The fact that two thirds of the programs changed or plan to change their sick call system indicates that there is probably no ideal system.

The discussion at the 1995

NEPPD meeting suggested possible remedies for abuse: explaining proper use of the sick call system- especially to incoming residents, private conversations between the resident of concern and chief resident or program director, scheduling a penalty payback for situations where abuse was detected, and putting abuse on the agenda in resident meetings. A suspected "abuser" should know that excessive absence may jeopardize his/her ability to complete the program in the usual time frame. The American Board of Pediatrics requires 33 months of training over three years, with 3 months allowed for absences such as vacation, sick leave and parental leave.²² Depending on vacation, this leaves only 10 to 15 working days of sick leave.

A well-working sick call system allows sick residents to stay home and recuperate while reducing the stress of feeling guilty about their absence.



Chief residents judged discussion of sick call difficult. Reasons for the difficulties were the risk of falsely accusing a resident of abusing sick call, suspected differences in the severity of illness that renders an individual resident unable to work, and the concern

that the chief resident may induce a resident to work when that resident is too ill to work properly. Chief residents also worried about: limit-setting for long term illness, the support for residents with chronic conditions, the criteria for non-illness absences- such as the degree of kinship

required for attendance of funerals, sanctions that might be applied to prevent or counteract abuse, and corrective measures for neglecting sick call duties. In 2 programs, written reports were placed into the permanent records of "abusers;" another program scheduled extra sick call duty as a penalty.

There are limitations to this data. Only chief residents were questioned, not other residents or program directors. The chief residents had been in their role only eight months of their one-year appointment. The questionnaires did not address parental leave policies and day time coverage for sick residents. Furthermore, they did not elicit if changes in sick call policy were made by decree or as a resident group decision, and how that influenced problems. The survey did not address how many residents actually used sick call over a period of time, the definition and characteristics of "abusers," the actual illnesses or other reasons for absence, and the rotations or seasons with more sick calls than others. The latter two questions, however, have been explored in a pediatric residency in the past.²¹

The Residency Review Committee for Pediatrics of the Accreditation Council on Graduate Medical Education's revised requirements for pediatric residency programs went into effect February 11, 1997.²⁰ They specify: "There should also be a resident back up call schedule or alternate plan to provide coverage in the event that the assigned resident is unable to fulfill the assignment." However, sick call is more than an administrative issue. A sick call system allows sick residents to recuperate and reduces their guilt about their absence. Ideally, it deters residents from abusing their colleagues by imposing an extra burden during one of the most stressful periods of their careers. It can bolster morale in a residency program.



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Brown University Second Annual Research Symposium on Mental Health Sciences: Abstracts

Introduction

— Martin B. Keller, MD

The Brown University School of Medicine Department of Psychiatry and Human Behavior (DPHB) was pleased to present The Second Annual Research Symposium on Mental Health Sciences on November 19, 1997. Brown University Faculty presenters were Barry Lester, PhD, Tracie Shea, PhD, Peter Monti, PhD, and David Abrams, PhD. The symposium also featured over 100 research abstracts and posters by faculty, post-doctoral fellows, residents, psychology interns and medical students from Brown University. Overall, 200 members of the Brown University and Rhode Island health care communities exchanged ideas on new research and treatment in the field of behavioral sciences.

As part of its mission, The Department of Psychiatry and Human Behavior is dedicated to improving the mental health of the population, both in Rhode Island and nationally. We are committed to advancing the care of patients of all ages, addressing the needs of underserved populations and to overcoming the stigma of mental illness and its treatment. The Research Symposium on Mental Health Sciences exemplifies this commitment. Our faculty and trainees are leaders in their respective areas of behavioral and mental health research. We are pleased to share their expertise with the Rhode Island health care community.

The DPHB was honored to host guest speaker, Alan I. Leshner, PhD, Director of the National Institute on Drug Abuse (NIDA), National Institutes of Health. As director of NIDA which supports over 85% of the world's research on the health aspects of drug abuse and addiction, Dr. Leshner's presence at the symposium highlighted the need for researchers in the field of mental health to consider the importance of addiction medicine. Dr. Leshner addressed the need to bridge the gap between the revolutionary advances in the treatment of substance addiction and the manner in which this national problem is still handled in the public and private sector. Much of the addiction and substance abuse work done in our department is conducted through the collaboration of the Brown University Center for Alcohol and Addic-

tion Studies and the Miriam Hospital Division of Behavioral and Preventive Medicine. This collaboration is a model of how Brown University strives to create centers of excellence to achieve a critical mass of talented individuals pursuing a common goal.

As Chairman of the Department of Psychiatry and Human Behavior, I am proud of the research and teaching being conducted by our faculty and trainees. The success of the Research Symposium on Mental Health Sciences and the findings reported by our presenters mark the need to continue to pursue research that helps us understand the etiology, pathophysiology and treatment of mental disorders.

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Drugs and the Brain: Can Science Replace Ideology?

— Alan I. Leshner, PhD

DRUG ABUSE is one of the most serious and pervasive health and social problems facing our nation. It contributes to increased morbidity, mortality, crime, violence, accidents and transmission of pernicious communicable disorders, such as hepatitis, tuberculosis, and HIV/AIDS. These problems, in turn, lead to increased societal costs for law enforcement and health care. Fortunately, substantial progress is being made to identify and develop effective strategies for the prevention and treatment of drug abuse and addiction. Over the past several decades, advances in neuroscience and behavioral science have revolutionized our views of drug addiction and its treatment. However, many of the field's most notable discoveries are well kept secrets, largely unknown by the public and even the practitioner and the policy and advocacy communities. There is a unique "disconnect" that exists between the public's perception of drug abuse and the strides that science has made to combat this national crisis.

Discussion focused on the biological, behavioral and social mechanisms of drug abuse and addiction and their implications for prevention, treatment and policy.

Alan I. Leshner, PhD, is Director, National Institute on Drug Abuse, National Institutes of Health.

The Collaborative Longitudinal Study of Personality Disorders

— Tracie Shea, PhD

THIS PRESENTATION DESCRIBED the aims, design and methods, and preliminary findings from a major new collaborative longitudinal study of personality disorders. Participating sites, in addition to Brown University, include Harvard, Columbia, Yale and Vanderbilt Universities. The primary aims of the study are to examine the stability of personality disorder diagnoses and criteria; to describe the course of these disorders in terms of impairment in functioning, comorbid Axis I diagnoses, and utilization of health care resources; to examine hypothesized predictors of course; and to examine the validity of the disorders under study as defined by their descriptive features, stability over time, and outcome. A total sample of

750 subjects is being recruited and followed at 6, 12, 24, and 36 months. The target sample will include 150 of each of the four personality disorders under study: Schizotypal (SZT), Borderline (BPD), Avoidant (AVPD), and Obsessive-Compulsive (OCPD) personality disorders. The control group will consist of 150 subjects with Major Depressive Disorder, without personality disorder. Subjects receive comprehensive assessments at intake and at each follow-up evaluation, including measures of Axis I and Axis II disorders, personality traits, various aspects of social functioning, traumatic experiences in childhood and adulthood, life events occurring during the follow-up intervals, mental health treatment, and other service utilization.

Preliminary findings are based on intake assessments of over 350 subjects. Consistent with prior studies, we find high rates of comorbid Axis I disorders, particularly mood and anxiety disorders. Rates of current mood disorder (any type) range from 46% of OCPD subjects to 74% of SZT subjects; current anxiety disorder (any type) is present in 62% of study subjects. Fifty-four percent of study subjects have a current or past diagnosis of alcohol or drug abuse/dependence, ranging from 36% of the OCPD subjects to 66% of the BPD subjects. Also consistent with prior studies, there is considerable overlap among the Axis II disorders, with most subjects meeting criteria for more than one personality disorder. Comparisons among the four personality disorder groups under study on measures of functioning (e.g. employment; relationships with spouse, family, friends; life satisfaction) show a consistent gradient, with SZT being the most impaired, followed by BPD. AVPD subjects are intermediate, while OCPD subjects show the least impairment of the personality disorder groups. Regression analyses were conducted to examine the association between SZT cell assignment and functioning measures, controlling for the number of current Axis I disorders and number of comorbid Axis II disorders, to determine if these factors might explain the increased levels of impairment in this group. SZT cell assignment remained significantly predictive of worse functioning even when these variables were controlled.

Tracie Shea, PhD, is Associate Professor of Psychiatry and Human Behavior, Brown University, and Psychologist, Post Traumatic Stress Disorder Clinic, VA Medical Center.

Reaching Substance Abusing Teens in Medical Settings Through Motivational Intervention

— Peter M. Monti, PhD

HEALTH CARE SETTINGS provide an opportunity to reach individuals who are in need of substance abuse interventions but are not served by other sources. Indeed, several studies have demonstrated the efficacy of brief interventions for adult substance abusers in medical settings. Both adult smokers and alcohol abusers have been served effectively.

Preliminary work conducted in our laboratory has underscored the prevalence of alcohol involvement and/or smoking with teens visiting the Emergency Department (ED) at Rhode Island Hospital. Indeed, teens who were alcohol positive (either due to a positive BAL or because they reported alcohol use at the time of their injury) drank significantly more days per month and had more drinks per day than alcohol negative teens. Furthermore, alcohol positive teens were drunk on more of these days as well. In addition, alcohol positive teens had significantly more alcohol related injuries over the past year and engaged in significantly more reckless behaviors. Similarly, the prevalence for smoking among teens in our ED is exceptionally high. Across a range of studies, approximately 41% of our teens are current smokers, as compared to approximately 23% in RI in general.¹

Given the high prevalence of these behaviors and the unique opportunity that an ED environment presents, brief motivational interventions were developed for each of these types of abuse. Motivational interviewing (MI) combines personalized feedback regarding substance use effects with an empathic, nonconfrontational therapeutic style.² The brevity of MI, less than an hour total, makes it particularly suitable for use in a busy medical setting.

Two distinct studies were conducted with conceptually similar interventions. Study I involved a 45 minute MI with alcohol positive 18 and 19 year old patients. Eighty patients were randomly assigned to either a brief MI or to a standard care comparison group and then followed up at 3 and 6 months post intervention. Personalized feedback components were based primarily on feedback about drinking levels relative to age and gender based norms and concerning personal negative consequences and risks experienced, such as injuries. Follow-up rates at 3 and 6 months were 91%

and 87%, respectively. At 3 months the groups were significantly different with regard to their drinking frequency. This difference was not significant at 6 months. However, at 6 months the groups were significantly different with regard to alcohol-related problems and alcohol-related injuries. All differences favored patients in the MI group.

Study II involved a similar MI with teen smokers who happened to be visiting any one of three different hospital settings. Forty teens, ranging in age from 14 to 17 years were randomly assigned to either a brief MI or to a Brief Advice contrast group and then followed up at 3 months. Personalized feedback components were based on an exploration of the teen's smoking, eliciting the teen's goals, identifying barriers, and discussing strategies. Primary outcome measures included a measure of tobacco dependence, number of serious quit attempts, and number of days smoked per week. Follow up rate at 3 months was 95%. The groups differed on 7-day point prevalence for smoking cessation and on our measure of tobacco dependence, suggesting that MI teens were responsive to the intervention.

The preliminary results from this research with adolescent substance abusers in medical settings are promising. Both interventions proved feasible and well accepted by both adolescents and their parents. The high rates of recruitment and retention at follow up are encouraging as well. Drinking differences and changes in alcohol related problems and injuries in the alcohol study and differences in quit attempts in the smoking study support the notion that brief motivational treatment can work with adolescent substance abusers.

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Peter M. Monti, PhD, is Professor of Psychiatry and Human Behavior, Brown University, and Associate Director, Center for Alcohol and Addiction Studies.



Nicotine Dependence: Integrating Biomedical and Public Health Paradigms for Research and Practice

— David B. Abrams, PhD

THREE DECADES OF RESEARCH on tobacco dependence can provide insights into the conceptual, clinical, and service delivery challenges facing addiction research for the 21st century. Biological sciences, cognitive-behavioral, clinical treatment outcome, and public health arenas are selectively reviewed. The key conceptual issues are explored relevant to research needed to inform the optimal delivery of interventions for the general population of adult smokers at reasonable cost. A comprehensive, ideal model to inform research and practice is developed. The model consists of an overarching public health approach, focusing on enhancing motivational level - from low motivation to quit to high motivation. Smokers are then assessed and triaged into one of three treatment steps of minimal, moderate, and maximal intensity

and cost. Smoker individual differences at both the population and individual level are also taken into account as part of a tailoring or matching strategy within and across the stepped interventions. Smoker profiles include sociocultural, nicotine dependence, and comorbidity factors. The result is a hybrid stepped-care matching model.

The model illustrates some of the needs and challenges facing future tobacco dependence research and practice. A common outcome metric of overall impact is also proposed to facilitate comparisons between clinical and public health interventions. The conceptual principles identified in this discussion could be used as a guidepost for research in other addictive behaviors and are also relevant to the evolving managed health care system.

David B. Abrams, PhD, is Professor of Psychiatry and Human Behavior, Brown University, and Director of the Division of Behavioral Medicine, The Miriam Hospital.

Prenatal Drug Exposure and Child Outcome: The Maternal Lifestyles Study

— Barry Lester, PhD

THE MATERNAL LIFESTYLES STUDY (MLS) is a multi-center longitudinal observational study of the sequelae of intrauterine polysubstance exposure on the outcome of infants and their families from birth to three years of age. The strengths of the MLS include variability in and measurement of potentially confounding variables that could interact with the effects of cocaine in explaining child outcome. These include other drugs, social class, race and ethnicity, and maternal child interventions. Meconium toxicology and post partum maternal interview is used to determine drug exposure; and preterm as well as term infants are studied. A neurodevelopmental battery, specifically designed to test hypothesized drug effect, supplements pediatric follow-up. The battery includes measures of child behavior and physiology during steady state and stress conditions along dimensions of arousal, attention/cognition, and social emotional and motor outcomes as well as measure of parenting and the caregiving environment.

Phase I of the MLS study screened over 19,000 women, conducting independent infant exams and collecting hospital data on the history of pregnancy, drug and alcohol exposure, the results of routine infant exams and meconium tests for drug exposure. From this sample, a cohort of 1400 mother-infant dyads, those exposed to drugs and their controls, were enrolled and followed in a one-month-to-one-year Phase II study. The nine-visit Phase II includes standard medical follow-up and case management as well as the neurodevelopmental measures. After the first two and one half years of Phase II, the overall compliance rate was 81%. Phase II will be completed in the fall of 1998. Preliminary findings through one month of age were presented suggesting that the effects of cocaine are subtle.

Barry Lester, PhD, is Professor of Psychiatry and Human Behavior and Pediatrics, Brown University, and Director of the Infant Development Center, Women and Infants' Hospital.





THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... — WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

⌘ A Fatal Case of *Rhodotorula* Meningitis in AIDS ⌘

Aijaz Ahmed, MD, Meenakshi Aggarwal, MD, Rex Chiu, MD, Bharat Ramratnam, MD,
Michael Rinaldi, MD, and Timothy P. Flanigan, MD, MPH

As patients with AIDS live longer with prolonged immunosuppression and prophylaxis, unusual opportunistic infections are being reported. In particular, the long term use of fluconazole has resulted in resistant fungal infections. *Rhodotorula* is a yeast in the same family as *Cryptococcus*, although it is frequently not susceptible to fluconazole.¹ As this case demonstrates, rare fungal infections may occur in patients with AIDS despite antifungal prophylaxis. This is the second case of *rhodotorula* meningitis reported in a patient with AIDS; and the first description of death directly due to *rhodotorula* meningitis in AIDS.

CASE REPORT

A 37 year old white woman who had HIV infection from intravenous drug use was admitted for evaluation of headache, neck pain and generalized weakness. Her most recent CD4 count was 30. She was taking fluconazole (100 mg per day) for over 6 months due to recurrent esophageal candidiasis; other medications included ddI and dapsons. She had no other opportunistic infections. BP=100/60 mm Hg, HR=120 beats/min, Temp=97F and Respiration 24 breaths/min. She complained of neck stiffness and had meningeal irritation on examination. CT scan of the head was normal. Lumbar puncture showed 38 WBC/mm³ with no RBC, 4% PMNs, 84% lymphocytes, 6% monocytes, glucose 10 mg/dl, protein 71 mg/dl, negative india ink stain and no organisms on gram stain. The blood leukocyte count was 32,600/cu mm with 29% bands.

She initially received amphotericin B for 2 days. When subsequent cryptococcal antigen latex test in the cerebrospinal fluid was reported negative, her antifungal therapy was changed to fluconazole. She also received empiric therapy for bacterial, HSV and CMV infections. A repeat lumbar puncture was consistent with meningitis with a low glucose and an elevated WBC. She continued to deteriorate and became obtunded - dying on day 14 of the admission. Post-mortem, *Rhodotorula* sp. was isolated from the lum-

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
CMV	cytomegalovirus
CSF	cerebrospinal fluid
HIV	human immunodeficiency virus
HSV	herpes simplex virus

bar puncture CSF specimen. The *Rhodotorula* sp. was resistant to fluconazole (minimal inhibitory concentration at 24 hours 20 mcg/ml and at 48 hours 40mcg/ml) and susceptible to amphotericin B (minimal inhibitory concentration at 24 and 48 hours <0.14 mcg/ml). An autopsy was not performed.

DISCUSSION

As patients with AIDS live longer with prolonged immunosuppression and prophylaxis, unusual opportunistic infections are being reported.



The genus *Rhodotorula* is a member of the subfamily *Rhodotorulodeae* and family *Cryptococcaceae*.² Numerous species of the pink *Rhodotorula* genus have been isolated and described.³ *Rhodotorula rubra* and *Rhodotorula glutinis* are the most commonly reported species. *Rhodotorula* is an airborne yeast commonly seeding skin, lungs, urine and feces in a normal host. The pink fungus has also been isolated from milk, cheese, soil and water.

On examination of the cerebrospinal fluid (CSF) with india ink stain, *Rhodotorula rubra* is indistinguishable morphologically from *Cryptococcus neoformans*.⁴ The latex test for cryptococcal antigen can be falsely positive in *Rhodotorula rubra* infection.⁵ Hence, *rhodotorula* meningitis can be misdiagnosed as cryptococcal meningitis. However, in our case the latex agglutination test for cryptococcal antigen was negative. The differential diagnosis of *rhodotorula* from cryptococcal meningitis depends on inositol assimilation test. A lack of inositol assimilation by the isolate confirms the presence of *Rhodotorula* sp.⁴

The literature reveals that *Rhodotorula* septicemia can result from contaminated intravenous infusion apparatus.¹

The majority of patients with *Rhodotorula* septicemia had serious medical conditions requiring extended intravenous drug therapy. Most patients had neoplastic disease; others had endocarditis, unknown pulmonary disease, gunshot wound and AIDS.^{1,5,6,7,8} In HIV-infected individuals *Rhodotorula* sp. has been isolated from blood, CSF, urine and peritoneum.

Mycotic meningitis most commonly results from *Cryptococcus neoformans*.⁴ The first report of *Rhodotorula* sp. isolation from CSF was documented in 1960: the patient recovered from meningoencephalic irritation without specific treatment.⁹ A second case was reported in 1968 documenting a rhodotorula meningitis in a 21 year old caucasian male with acute lymphoblastic leukemia. This patient received over 2000mg of amphotericin B intravenously (including 25mg intrathecally) for six months prior to death. At autopsy, *Rhodotorula* was stained and shown to extensively invade the meninges.⁴ The debilitated condition of the patient was considered a contributing factor in his failure to respond to therapy. A disseminated *Rhodotorula rubra* infection with meningeal and urinary tract involvement has been described in a patient with AIDS.⁵ The patient received a total of 1500 mg of amphotericin B intravenously followed by suppressive therapy with amphotericin B (100 mg weekly for 4 months). Later, the patient received oral fluconazole (100 mg per day for additional 10 months). The patient remained asymptomatic for the next 4 years, at which point the case was reported in the literature.

Amphotericin B is considered the drug of choice in rhodotorula infection.⁵ However, dosage and duration of amphotericin B are not well-defined. 5-fluorocytosine has also been shown effective in treating rhodotorula infection. There has been documentation of resistance of *Rhodotorula* sp. to fluconazole.¹ The *Rhodotorula* sp. isolate in our patient was resistant to fluconazole and susceptible to amphotericin B, in vitro.

In conclusion, as patients with AIDS live longer with prolonged immunosuppression and prophylaxis, unusual opportunistic infections are being reported. In particular, the long term use of fluconazole has resulted in resistant fungal infections. *Rhodotorula* sp. is frequently resistant to fluconazole. Prophylactic therapy with fluconazole may result in more frequent infections with *Rhodotorula* sp. Heightened awareness of this infection may result in a prompt diagnosis and appropriate therapy with amphotericin B.

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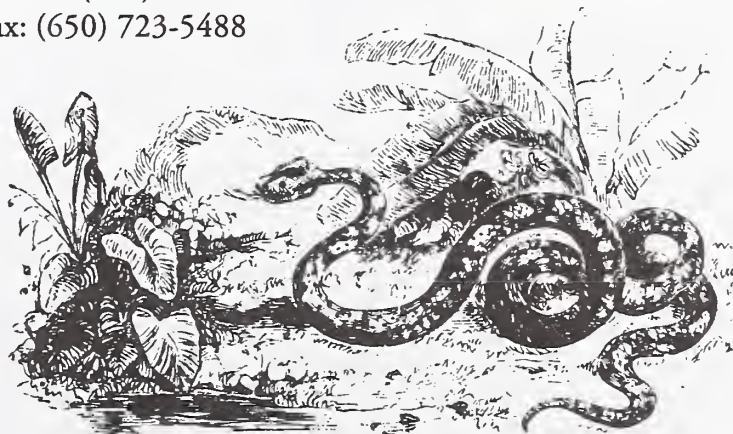
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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Health Status and Health Risk Behaviors Among Minority Rhode Islanders, 1996

Hanna Kim, PhD, and Jana E. Hesser, PhD

Reducing health disparities among Americans is a national and a Rhode Island health objective for the Year 2000.^{1,2} Black and Hispanic Rhode Islanders have poorer health outcomes than do white, non-Hispanic residents as measured by a wide variety of health indicators.³ Those poorer health outcomes can be attributed to limited access to adequate health care, to environmental factors, and to individual health risk behaviors. This paper presents survey data from 1996 on health status, health risk behaviors, and health care access for black, Hispanic, and white non-Hispanic Rhode Islanders.

Methods

The Behavioral Risk Factor Surveillance System (BRFSS) is a national effort, funded by the Centers for

Disease Control and Prevention (CDC), to monitor population trends for key health risk behaviors, health insurance coverage, and participation in health screening.⁴ In 1996, all 50 states and 4 territories participated in the BRFSS; Rhode Island has participated since 1984. Each month, the BRFSS conducts telephone interviews with approximately 150 randomly selected Rhode Island residents aged 18 and older, for a total of 1,800 each year. In 1996, additional interviews were conducted to increase the reliability of survey data for minorities, for a total of 2,482 interviews. This included interviews with 1,624 white non-Hispanic respondents, 277 black non-Hispanic respondents, 444 Hispanic respondents, and 137 respondents in other race/ethnicity groups. Methods used for the BRFSS are defined by CDC and followed by all states participating in the BRFSS. Results for Rhode Island are reported annually.⁵ This report contains statistics from the 1996 BRFSS on twelve major health risks, comparing results for white non-Hispanics, black non-Hispanics, and Hispanics.

Results

Each racial/ethnic group has a distinctive prevalence pattern for the 12 health-risk behaviors included here (Table 1 and Figure 1). Risk factor prevalence rates for black and Hispanic groups are not always higher than those for the white non-Hispanic majority, and the rates often differ between the two groups.

Both blacks and Hispanics have higher rates than the white non-Hispanic population for six of the twelve measures — fair or poor general health status, no health care coverage, sedentary life style, overweight, eating few fruits and vegetables, and being at increased risk of HIV infection. Black Rhode Islanders are also more at risk than the white non-Hispanic population for smoking, diabetes, and not having a Pap test in the past 2 years. However, white non-Hispanics are at

**TABLE 1:
HEALTH STATUS AND HEALTH RISKS AMONG RHODE
ISLANDERS, BY RACE/ETHNICITY, 1996**

**BLACKS HAVE HIGHEST
RATES FOR:**

- Current smoking
- Having diabetes
- Being overweight
- Eating few fruits and vegetables
- No Pap smear in past 2 years

**HISPANICS HAVE HIGHEST
RATES FOR:**

- Poor general health
- Being uninsured
- Sedentary life style
- Higher chance of HIV infection

**WHITES HAVE HIGHEST
RATES FOR:**

- No routine health checkup within past year
- Having arthritis
- No mammogram in past 2 years

Risk factors are defined as follows:

General Health Status: Self-rated general health is fair or poor.

Routine Checkup: No routine health checkup within past year.

Uninsured: Has no health care coverage.

Current Smoker: Smokes cigarettes regularly or occasionally.

Diabetes: Ever told by physician has diabetes (includes gestational).

Arthritis: Ever told by physician has arthritis.

Overweight: Body-mass index ≥ 27.3 for females, ≥ 27.8 for males.

Sedentary Lifestyle: Has little or no leisure-time physical activity.

Fruits & Vegetables: Eats fruits and vegetables less than three servings a day.

HIV: Self-rated chance of infection with HIV is medium or high.

Pap Smear: No Pap test in past 2 years -- women with intact uterine cervix.

Mammogram: No mammogram in past 2 years -- women, age 40+.

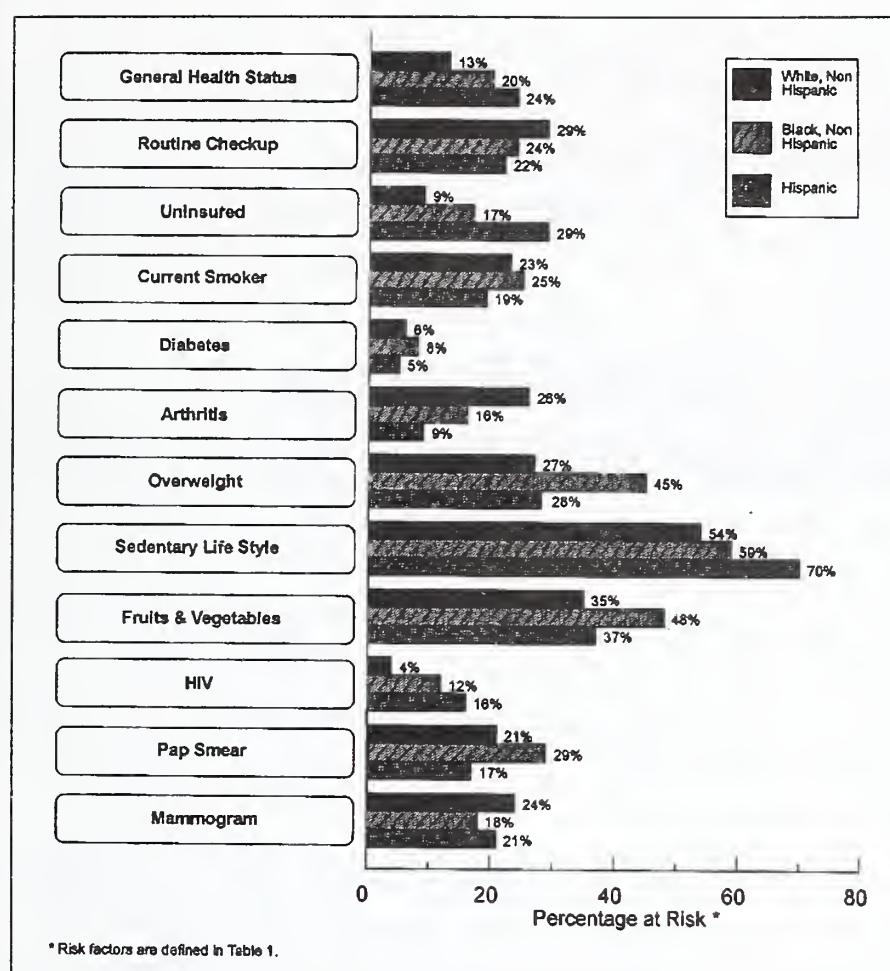


Figure 1. Health Status and Health Risk Behaviors among Rhode Islanders, by Race/Ethnicity, 1996.

highest risk for three measures — not having had a routine checkup in the past year, not having a mammogram in the past 2 years, and for having been told by a doctor that they have arthritis.

For some measures, the disparities are especially large. The percentage of black Rhode Islanders who perceived themselves as being at high or medium risk for HIV infection (12%) is three times the percentage for whites (4%); for Hispanics the percentage is four times that for whites (16%). The percentage of blacks with no health insurance coverage (17%) is nearly twice as high as for non-Hispanic whites (9%), and the percentage for Hispanics (29%) is more than three times as high. Nearly one half of black Rhode Island adults (45%) are overweight compared with just over one quarter for both white non-Hispanics (27%) and Hispanics (28%). Nearly one-half of blacks (48%) eat few fruits and vegetables compared with approximately one third of whites and Hispanics. More than two thirds of Hispanics (70%) have a sedentary lifestyle, compared with 53% of whites and 59% of blacks. Hispanics also reported the highest rate of self-rated poor health status (24%) compared with 20% of blacks and 13% of whites.

There are considerable differences among the three groups in their utilization of health services. Both blacks and Hispanics in Rhode Island are more likely to have had a routine health checkup or mammogram than whites, and Hispanics have the lowest rate (17%) of the three groups for not having had a Pap smear in the past 2 years, while the rate for blacks is the highest (29%). Relatively high

rates for minority participation in health screening activities may be the result of specific efforts currently underway in the state which target minorities. For example, the RIte Care program of the Department of Human Services, established in August 1994, is designed to make health insurance available to more Rhode Islanders with low incomes. The Women's Cancer Screening Program in the Department of Health is designed to increase the availability of free screening opportunities to low income and minority groups. Further, since 1994, the Department of Health, through its minority health promotion grant program, has awarded 51 health promotion and disease prevention grants to 23 community-based agencies serving racial/ethnic minority populations. One of the objectives of these grants is to improve access to health care among minority populations. Results of the 1996 BRFSS indicate that these and other such efforts may be succeeding.

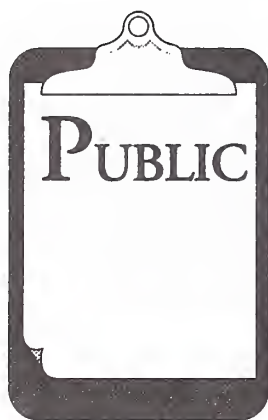
However, for the majority of BRFSS measures of health status, health risk behaviors, and health care access, minority racial/ethnic populations remain disadvantaged. Preliminary national health objectives for 2010 propose to eliminate such disparities in health in our population.⁶ As documented by the BRFSS, to do so in Rhode Island will require a substantial enhancement of health promotion programs targeting these groups over the next decade.

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Can Communities Afford Population-Based Primary Health Care?

Michael Fine, MD and Sam Mirmirani, PhD

The struggle to rationalize health care in the U.S. has focused on reimbursement; i.e., on how health care providers will be paid. With this focus, a rational system of health care distribution has been neglected. Its absence has produced the chaos of the health care marketplace: multiple providers contending for turf, costs exceeding 14% of the gross national product,¹ and a weak relationship between costs and the control of disease.

Reimbursement systems cannot address the critical elements of a rational health care system, which include: affordability, accessibility, fair distribution, respect of participants' autonomy, and effectiveness in controlling the incidence and prevalence of disease.²⁻⁶ The social imperative for health security, and the failure of the marketplace

to address this imperative, have paved the way for the creation of managed care.

Managed care organizations (MCOs) profit by creating a rational health care system for subsets of a society that has failed to accomplish this task for society as a whole.

Failure of health care reform at the national level has precluded a centrally organized health care distribution system with universal access to care. Failure at the national level, however, does not preclude reform at regional, state, and local levels.

Abbreviations Used:

CHC	community health center
MCO	managed care organization

Table 1
Available cost estimates of primary health care, 1995

Source	1995 cost per person/year
Medical Group Management Association ⁹	\$139
Publicly funded community health centers ¹⁰	\$310
Estimated primary health care capitation rates ¹²	\$108-192

Table 2
Cost of other population based services,* per person/year, 1993 data adjusted for inflation to estimate 1995 costs

Service	1993 cost per person/year, adjusted to 1995
Elementary and secondary education	\$988
Highways	\$285
Police and fire protection	\$219
Corrections	\$123
Housing and community development	\$78
Parks and recreation	\$67

*Data from the Rhode Island Public Expenditure Council

In this report, we present very preliminary evidence that the patient/year cost of *primary* health care may be of the same order of magnitude as other services usually provided by local communities, and thus may be considered affordable by them. On the basis of that evidence, we argue that the provision of *population-based primary health care* by regional, state, or local governments can serve as the basis of health care reform in this country.

What is population-based primary health care?

Population-based primary health care is that system of health care distribution which assigns every person residing in a geographical area to a population-based primary health care practice located in that geographical area, and makes every population-based primary health care practice located in a geographical area responsible for the primary health care of every person residing in that geographical area. Such a system, if implemented, must provide for patient choice in the selection of a primary health care practice.

Because there is no population-based primary health care system in the United States, the cost of population-based primary health care is unknown. The order of magnitude of its cost, however, may be extrapolated from the costs of providing primary health care in other systems.

What does primary health care cost?

For the purposes of this report, the cost of providing primary health care covers: salaries and benefits of providers and support staff, office space, malpractice and other insurance, medical and business supplies, taxes, depreciation, financing, and continuing medical education.⁷

The most significant determinant of patient/year cost is the number of patients served by a provider. Because this number usually ranges from 1500 to 2500,^{8,9} only very large changes in line item expenditures yield order of magnitude changes in the patient/year cost.

Nationally, there are few data on primary health care cost per patient, per year, and the existing data lack standardization, making comparisons quite complex. Much of the available cost information is charge-based, not cost-based.

Estimates of primary health care costs are constructed from the cost of available primary health care services and the case mix of populations served. In our estimates, we do not include the costs of laboratory, physical therapy, or "primary care" radiology. If included, these services would increase the patient/year cost of primary health care.

The most comprehensive cost data are compiled annually by the Medical Group Management Association. Their 1996 data, based on the 1995 activities of 4843 group practices, represent about 22% of all practices in the Association. Of these, the only single-specialty primary health care discipline reporting a population base was family practice, and only 11 family practices reported a population base. For these 11 practices, the median patient/year cost of primary health care was \$139 in 1995.⁹

The Bureau of Primary Health Care of the United States Public Health Service collects and reports the experience of the nation's publicly funded community health centers (CHCs), which altogether serve about eight million people.¹⁰ This socially and economically stressed population bears a heavier burden of disease than more affluent populations. As a result, CHCs usually offer services not found in other primary health care systems, including nutrition, transportation, and social work. The 1995 patient/

year primary health care cost of CHCs around the nation was \$310.

Primary health care capitation rates reflect costs as experienced by managed care organizations, *not* costs as experienced by providers. Thus, they may reflect market forces and profit incentives as well as actual costs. In addition, primary care capitation rates are adjusted for the age and sex distribution of the populations served, and vary from payer to payer in the services covered.¹¹ At best, capitation rates are proxies for patient/year cost. They are also highly proprietary, with no independent, objective documentation available. However, most primary health care physicians

work with these rates, and review them with their national organizations. Experienced observers believed these rates to range from \$9 to \$16/patient/month in 1995.¹² This suggests a patient/year cost of \$108 - \$192, which is broadly consistent with the other patient/year costs of primary health care presented (Table 1).

The data from these three lines of evidence are patient-based, *not* population-based in a geographical sense. This artificially shrinks the denominator, while under-reporting the costs of providing care to the portion of the population which does not seek care. The relationship between the costs reported herein and those which would be experienced by a population-based primary health care system is unclear.

In addition, the data from the Medical Group Management Association and from the Bureau of Primary Health Care reflect reported costs from open access populations which are not locked into the primary health care systems from which the data are reported. These populations may be incurring additional, unreported primary health care costs elsewhere. In short, data from the Medical Group Management Association and from the Bureau of Primary Health Care may underestimate the actual cost of primary health care to the populations served.

These lines of evidence suggest the *order of magnitude* of primary health care costs, and should not be construed to supply precise cost estimates.

What do other population-based services cost?

The expenditures for other population-based services (Table 2) are national averages calculated from statistical information on state and local government spending for fiscal year 1993, published by the Governments Division of the United States Census Bureau.¹³ The services are clearly and narrowly defined. These data are truly population based.

*Population-based
primary health care is
that system of health care
distribution which
assigns every person
residing in a geographical
area to a population-
based primary health
care practice located in
that geographical area,
and makes every
population-based
primary health care
practice located in a
geographical area
responsible for the
primary health care of
every person residing in
that geographical area.*



We have adjusted the 1993 data for inflation at 3% per year to allow comparison with the 1995 data reported above. This adjustment was made to facilitate comparison only, and may not reflect actual expenditures.

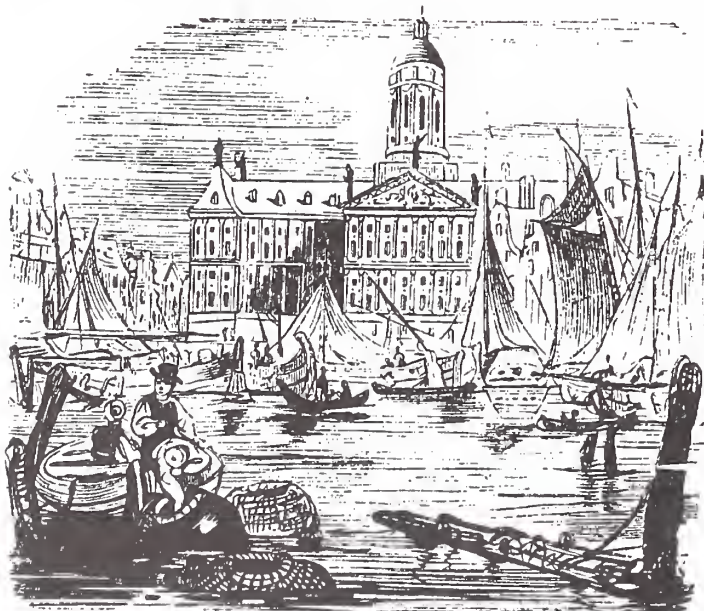
Conclusion

In this report, we present three preliminary lines of evidence suggesting that primary health care may be affordable, and further, that its costs may be on the same order of magnitude as other universally accepted population-based services provided by state and local governments. On the basis of this evidence, we suggest rethinking the financing of primary health care.

While the actual costs of a population-based system of primary health care are unknown, it appears that such a system could be built from the bottom up by local communities providing population-based primary health care for themselves. We believe national health care reform would move forward if it focused on creating incentives for state governments to plan and local communities to organize population-based primary health care infrastructures. To make primary health care universally accessible and population-based might change the essential dynamics of the health care marketplace.

Needed Research

Many factors contribute to the cost of providing primary health care. These factors include (but are not limited to) practice size and case mix, extent of services provided, provider composition and salary, managed care penetration, local overhead costs, and provider workload.⁷ Because primary care is a critical part of the public health and health services distribution infrastructure, we suggest creating a primary health care cost database that controls for practice size, composition, regional cost, and workload variables, so that clear conclusions about primary health care costs and efficiencies can be drawn.



Population-based primary health care does not exist in the United States. Before such a system can be advocated, careful cost projections must be drawn from a well constructed primary health care cost database. To that must be added the cost of system administration, as well as a macro-econometrics analysis of the effect of such a system on the economies of the health care market and the nation as a whole.

Still, population-based primary health care seems a viable and potent method for improving access without increasing costs. As such, its value should be further explored.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events

	Reporting Period		
	July 1997	12 Months Ending with July 1997	
	Number	Number	Rates
Live Births	1,125	13,528	13.7*
Deaths	754	10,055	10.2*
Infant Deaths	(8)	(88)	6.5#
Neonatal deaths	(7)	(71)	5.2#
Marriages	737	8,203	8.3*
Divorces	345	3,246	3.3*
Induced Terminations	436	5,670	419.1#
Spontaneous Fetal Deaths	67	1,047	77.4#
Under 20 weeks gestation	(60)	(960)	71.0#
20+ weeks gestation	(7)	(87)	6.4#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death

	Reporting Period			
	January 1997	12 Months Ending with January 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	353	3,382	341.5	4,485.5
Malignant Neoplasms	211	2,557	258.2	7,152.5
Cerebrovascular Diseases	70	612	61.8	996.5
Injuries (Accident/Suicide/Homicide)	39	343	34.6	6,024.5**
COPD	52	428	43.2	220.0

** Excludes 1 death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

THE RHODE ISLAND MEDICAL JOURNAL

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PROVIDENCE, R.I., JANUARY, 1917

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NINETY YEARS AGO

[JANUARY, 1908]

The lead article summarizes the work of the Providence physicians' committee, chaired by Dr. Charles V. Chapin, in furnishing clean milk for the babies of the community. Notices had been sent announcing the existence of the feeding stations, their locations and hours of operation to each local physician and to every mother who had given birth to a child on or after January 1, 1907. The centers were located on East St., Conanicut St, Eddy St, Delaine St, and Atwells Ave. They provided milk for 351 babies, 17 of whom died during the season. The total cost of the operation, including cost of milk, containers, refrigerators, ice, delivery costs and nurses salaries was \$2,281.18 while income [largely from 120 contributions] was \$2,181.17, leaving a grievous deficit of \$100.01.

Charles O. Cooke, MD, describes a case of appendicitis in a 30 year old woman pregnant 8 months. By the second day of observation there was pain over McBurney's point, fever and leucocytosis. A laparotomy was performed and after some difficulty a gangrenous appendix was identified and resected. Postoperatively the patient was given a saline drip per rectum. During the next evening labor began and the patient was delivered of a 4 lb. living baby. Patient recovered slowly and was out of bed by the 24th postoperative day.

Two cases of splenectomy are described by William L. Harris, who notes, in passing, that others have noted a heightened frequency of splenomegaly in Armenians and Sicilians, as well as in patients with leukemia and cirrhosis. The first case to be reported was a 34 year old woman with a large malarial spleen that needed resection. The second case was a 41 year old man with an enlarged spleen which, by microscopic examination proved to be tuberculous.

John W. Keefe, MD, describes the operative cure of a 26 year old teamster from Cape Verde Islands with a large popliteal aneurysm. The aneurysm was exposed surgically and the entrance to the sac obliterated by sutures [using the Matas method.] Patient was discharged 20 days after surgery, with the only complication an extensive ulceration over the gastrocnemius extending through the fascia.

FIFTY YEARS AGO

[JANUARY, 1948]

The bulk of the this special issue is taken up by an historic account of the Providence Medical Association, founded in 1848 and now in its one hundredth year of uninterrupted activity. The detailed review, written by Roland Hammond, MD, John E. Donley, MD, and Peter Pineo Chase, MD, begins with a description of a Monday evening meeting, January 31, 1848, in the North Court Street offices of Dr. H.W.Rivers. Attending were many of the local practitioners - how many is unknown - to form a local medical association "for the mutual benefit of its members." After the creation and approval of a constitution, taking many months before adoption, the Association established fee schedules recommended for its members [eg, \$1.00 per office visit; for night house calls, \$3.00; for pregnancy and deliveries, \$8.00.] At that time there were few inpatient institutions in Providence, a city of 40,000. There was Butler Hospital opened in 1847, Dexter Asylum for the sick poor, a pest house near Eddy St. for cases of small pox and typhus and for outpatient visits, the Providence Dispensary. The history then recounts the scientific meetings sponsored by the Association and the specific problems that it felt deserved considerable attention, such as the need to develop a coherent therapeutic plan for the care of patients with pneumonia. The report also reviewed the activities of the Association during the Civil War and the establishment of larger general hospitals such as Rhode Island Hospital [1865] and St. Joseph's Hospital [1892]. The need for a local medical journal was realized and in 1899 the *Providence Medical Journal*, edited by Dr. George D. Hersey, was established. The remainder of the report describes the many public health advances during this century, the role of specialization, the part played by physicians in insuring clean water and milk, the establishment of a state medical library and the active participation of Association members in the two world wars.

A companion article describes the history and accomplishments of the Providence City Health Department, from 1856 to 1948, under its eminent leaders: Edwin M. Snow, MD, Charles V. Chapin, MD, Dennett L. Richardson, MD, and Michael J. Nestor, MD.



TWENTY FIVE YEARS AGO

[JANUARY, 1973]

John A. Roque, MD, describes his experience with normal pressure hydrocephalus during a five year interval at Rhode Island Hospital, when he encountered 22 cases fulfilling the diagnostic criteria. In about one-third of these cases shunt procedures resulted in good to excellent clinical outcomes.

Joseph D. DiMase, MD, Hee K. Lee, MD, and Stephan I. Frater, MD, describe a case of choledochal cyst in a 12 year old girl. The diagnosis was established by hepatoscintigraphy, using I¹³¹ rose bengal.

In an article describing non-seasonal allergic rhinitis, Guy A. Settupane, MD, notes that the condition, like hay fever, asthma and atopic eczema, is believed to be an inherited or atopic disease. A detailed history and scrupulous allergic management are deemed necessary.

Gerhard C. Meier, MD, PhD, describes a case of encephalopathic, myelopathic and peripheral nerve dysfunction in folate deficient megaloblastic anemia in a 45 year old housewife. The patient responded well to folic acid administration.

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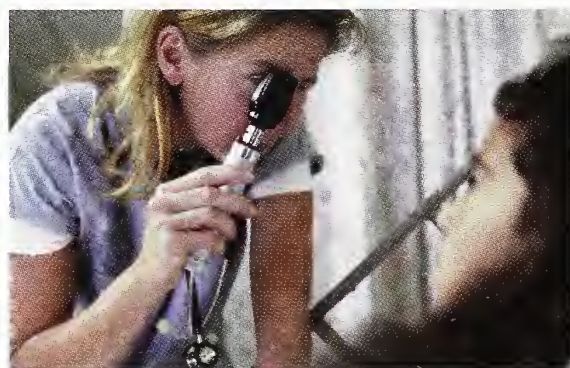


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COMMENTARIES

Drug Related Problems: Issues and Solutions

OVERVIEW

The clinician faces an ever increasing complexity of pharmacologic choices and therapeutic decisions. Drug interactions between prescription as well as over the counter medications can result in therapeutic failure or toxicity. Herbal remedies have gained public stature but remain uncontrolled. Patients are aging, with an increased risk of adverse drug outcomes. And non-adherence to medication regimens remains critical for patient management. This issue of *Medicine & Health/Rhode Island* is intended to address these drug-related issues and provide some practical solutions.

With the recognition of several subtypes of metabolic enzymes, available information regarding drug interactions has expanded both in volume and complexity. In the first article, Drs. McKindley and Dufresne outline the most important drug interactions confronting clinicians and provide tools to predict future drug interactions through identification and understanding of the cytochrome P450 isozymes involved in drug metabolism.

One of the most controversial areas in pharmacologic therapy today is that of alternative medicines. Despite the lack of scientific evidence for safety and efficacy, popularity of these products among consumers is growing. Dr. Glen and her colleagues define terms frequently used and confused by consumers and describe the legal context of alternative medicines. This overview discusses some of the most popular herbal treatments, with examples of their adverse effects. A practical approach to addressing the subject of alternative medicines with patients is also reviewed.

The population is aging, and clinicians face decisions regarding drug therapy based upon age-related changes in pharmacokinetics and pharmacodynamics. Adverse drug events are also far more common in elderly patients than younger patients. Dr. Luisi and colleagues address both issues. The authors review age-related changes in drug kinetics and dynamics, with pertinent examples. They evaluate two published methods used to reduce adverse drug effects in the elderly population.



Patient adherence to prescribed medical regimens is vital to the successful treatment of disease. In the final article, Drs. Geletko and Rana describe barriers to good medication adherence. Non-adherence is most frequent in individuals receiving complicated medication regimens. Using management of HIV infection as an example, the authors describe the consequences of non-adherence as well as strategies for improvement and application of these strategies to other disease states. Drs. Geletko and Rana conclude by discussing the Stages of Change Model, as a plausible predictor of a patient's adherence to medication.

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Vampire Capital of America

Back then, it wasn't known as the Ocean State. Far from it. In fact, newspapers of the 1890's dubbed Rhode Island "The Transylvania of the Western World" and "Vampire Capitol of America." In the 1800's Rhode Island's alleged vampires were not blood-sucking elected officials but rather real, true-to-life creatures of the darkness - undead, diabolical beings who stalked the state's moonlit, shadowy countryside in search of weary nighttime travelers whose souls were ripe for picking.

For one thing, the isolated country villages of South County [such as Coventry, Exeter, East and West Greenwich] physically resembled the lonely hamlets of Transylvania. This similarity inspired some east European immigrants to recall, and culturally transplant, many vampire legends from the old country.

For another thing, throughout the second half of the 19th Century, South County was subject to outbreaks of tuberculosis. As more young and previously healthy people were inexplicably swept away by pulmonary consumption, confused villagers sought explanations for the mysterious phenomenon.

The explanation that they came up with was vampirism: late night visitations by one of the living dead who would, it was believed, materialize in the bedroom of a healthy person and suck the life-force out of the victim by sitting atop the sleeping person's body, night after night until, through exhaustion, the victim died. The victim might also become a vampire attacking siblings as they slept. Tuberculosis was often a family disease, spread by close contact within the farmhouse.

At the peak of endemic tuberculosis [1870-1900] such beliefs gave rise to numerous vampire hunts and corpse exhumations throughout rural Rhode Island. The dead bodies of suspected vampires were unearthed and examined for signs of continued activity within the grave such as scratch marks on the inner coffin lid or continued growth of hair or finger nails after burial. The appearance of fresh, liquid blood was accepted as a sure sign of vampirism.

If the exhumed vampire could be identified, villagers believed, it could then be killed again by the removal and burning of its heart or liver [depending on which organ contained the fresh blood]. After the organ was burned, in a strange ritual that may have been derived from eastern Europe, the surviving family members then consumed the ashes often mixed with other medicines. The body of the alleged vampire, without its heart or liver, was then reburied; and it was believed that the vampire could then no longer be capable of leaving the grave to stalk its relatives.

During these years, the pages of such publications as *The Narragansett Times* and *The Providence Journal* contained numerous references to vampire-related activity in and around rural

South County. One such story concerned Snuffy Stukely, a farmer in rural Rhode Island. His wife had borne him 14 children and his farm had been equally fruitful. One night, however, Snuffy was confronted with an omen in the form of a dream. He dreamt of an orchard in which half of the trees were withered and dead, while the remaining trees remained healthy. When he awakened he was puzzled over the meaning of this dream but sensed that it portended some tragedy.

A few days later, Snuffy's oldest daughter, Sarah, sickened and perished. Shortly thereafter another of his daughters became sick. The second daughter, though, complained that, "Sarah comes to my room every night. She sits on different parts of my body and makes me hurt badly."

At first the parents attributed the visions to delirium; but shortly thereafter, the second daughter died.

One by one, goes the legend, Snuffy's children sickened and died until seven of his 14 offspring had perished. And each child, before dying, had described nightly visits from Sarah. Soon, Snuffy and his wife feared the worst: that Sarah had become a vampire and had made nightly visits to the Stukely household.

On one cold night Snuffy and several of his neighbors solemnly ventured into the small cemetery. They approached Sarah's grave and dug up the coffin. Upon opening the lid, they perceived Sarah's corpse with eyes wide open and hair and nails grown to unnatural lengths. When the body was prodded with a shovel, Sarah's lips

curled into a demoniacal grin. Surely she was a vampire.

According to the legend, the child's heart was then cut out but not before the vampire gave out a loud shriek. Then the body became lifeless. And when the ordeal was over Snuffy thought that he heard a whisper: "I am free. Thank you Daddy, and goodbye for now."

The farmer's prophetic dream of the half-dead, half-living orchard had been fulfilled. Half of his 14 children were dead; and the remaining seven would go on to lead healthy lives.

This story, like many Rhode Island accounts of its kind, was probably provoked by the documented outbreak of pulmonary tuberculosis in the rural reaches of the state and gave rise to gossip and speculation that these stricken families were victims of vampires. Eventually these incidents became embedded in Rhode Island folklore.

— Charles T. Robinson

Charles T. Robinson is an authority on the folklore and archeology of southeastern New England and is the author of best-selling texts on New England legends. This commentary was excerpted with permission from True New England Mysteries [Covered Bridge Press, 1997].

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Slouching Through Transylvania

No one listens to fanciful stories more avidly than the credulous child; and five year old Abraham, confined to his bed by some unknown bone disease, absorbed the daily tales related by his mother with uncritical wonderment. Mrs. Stoker had grown up in Sligo, Ireland; and as a child she had endured the collective miseries of the dreadful cholera epidemic of 1832. She shared with her son her remembrances of frightful tragedies befalling entire families; and she related the tales of rural communities hastily disposing of the contagion-ridden bodies. But, she whispered, some of these people were buried though still alive. She told, too, of spectral appearances, will-o-the-wisps, in the autumnal mists of western Ireland; of ghosts seeking justice, perhaps even vengeance; and she shared with Abraham her sense of disquiet that between the world of the living and the domain of the tranquil dead, there existed a place where the restless spirits of the undead might seek both sustenance and retribution.

Abraham's family were solidly middle-class Dubliners. One of Abraham's five brothers, for example, became an eminent surgeon, and all were well-educated. Bram [Abraham's nickname] majored in mathematics at Trinity. But then he disappointed his family deeply by seeking a career in repertory theater management, eventually supervising London's Lyceum Theatre and Henry Irving's troupe of actors. In his spare time he wrote novels, most of them lapsing into a duly deserved obscurity. However, one work of fiction managed to establish an enduring place



for itself in the genre of supernatural stories. Indeed, the story of Dracula looms more enduringly in history than its creator, becoming the preeminent horror tale of the 19th century.

The word vampire entered the English language in the mid 18th century reflecting the many legends of blood-seeking spirits said to terrorize the rural communities of the Balkan region. Vampire [*vampir*] is a Serbian word perhaps descended from an earlier Turkish word meaning a reanimated corpse. Of course there had been isolated tales from ancient Rome telling of incubi sucking the life from innocent sleeping victims, and fragmentary legends of robotic dybbuks in the Jewish ghettos, but nowhere but in rural southeastern Europe had such a widespread and fervent belief in vampirism taken root. Tales of vampires could be found in every village between the Transylvanian hills in the Hungarian west to the Ural mountains in the Ukrainian east.

By the time these vampire reports had reached gullible English ears, a consensus had been reached concerning the core characteristics of the typical vampire: It was generally a male who had recently died under socially undesirable circumstances [i.e., excommunicated by the Church, a declared sinner, an executed criminal, one who had committed suicide, or a victim contaminated by yet another vampire]. Shortly after death, but only between the hours of sundown and sunrise, did the restless, rejected and undead apparition rise to seek the needed blood of an innocent soul. Vampires slept during the day, generally in coffins containing soil from their original grave site. Vampires had notoriously bad breath and were capable, at will, of transforming themselves into either a wolf or a bat. Vampires were said to recoil at the sight of fresh garlic cloves or a crucifix. And finally, vampires could be vanquished only by driving stakes [preferably carved from aspen-wood] through their hearts, severing their heads, burning



their dismembered bodies and strewing the ashes at some intersection of roads. Some of the ashes, however, were preserved to be swallowed as an antidote to future vampire attacks.

The victims of the vampire, on the other hand, were said to be pallid, appearing as though they were afflicted with some wasting disease. They were frequently found at sunrise, drained of energy and with fresh blood stains upon their pillows. During the 18th century, many suffering from chronic tuberculosis were accordingly thought to be victims of vampirism. No questions seem to have been asked as to the mechanism by which the victim, having undergone venesection, was transformed into another vampire. Was some arcane toxin left in exchange, perhaps, for the extracted blood? Or was vampirism yet another bloodborne contagion?

While vampiric activities were even documented in colonial New England [see accompanying Commentary], the bulk of the legends were confined to the Balkans. Scholars have speculated that the rudiments of vampirism may have arisen in ancient Indus Valley sun-worshipping sects and then carried by certain nomadic tribes [the ancestors of the present-day Gypsies] in their migration west to their eventual homes in the Transylvanian highlands. Christianity had not been firmly established in this region until the 11th century.

Stoker's preoccupation with preternatural spirits arising from the grave led him to superimpose the vampiric myths upon an authentic piece of Rumanian history. One of the Wallachian bastions protecting Christian eastern Europe from the invading Turkish armies in the 15th century was ruled by a Count named Vlad the Impaler. Vlad's successful defense against the invaders transformed him into a national hero despite his acknowledged reputation as a tyrant

of unsurpassed cruelty. His historic sobriquet was based on his custom of impaling prisoners upon great stakes of wood atop the ramparts of his remote castle in the Transylvanian hills. The Holy Roman Emperor had previously inducted Vlad's father into the prestigious Order of the Dragon [the Greek word for dragon was *Dragos*. Those so inducted bore the title *Dracul*; the son of a *Dracul*, hence, was called *Dracula*.] Stoker had never visited Hungary or Rumania; but his many vacations to the town of Whitby in northern England, with its resident mists and abandoned hilltop castles, provided him with all the ambient features needed for his tale of horror.

Bats are inconsequential little rodents feeding mainly on insects and nectar. The Dracula tale, however, served to reinforce a longstanding, irrational anxiety about these creatures. Certainly their nocturnal habits and eerie capacity for flawless navigation in absolute darkness was a sure sign, people concluded, that they must be in league with malevolent forces. Biologists then showed that not all bats sustained themselves on innocent diets of insects and nectar; indeed, there were some species whose sole source of nutrition was animal blood. It took little imagination to rename them vampire bats. The sanguivorous species [*Desmodus rufus* and *Diphylla ecaudata*] are confined largely to the rural regions of Central America. These blood-using creatures actually do cause much economic harm, but not because of their blood-letting capacities. First, they are incapable of sucking blood; rather, they pierce the skin while simultaneously injecting an anesthetic agent and an anticoagulant. They then lap up the resultant capillary ooze, rarely absorbing more than a fraction of a teaspoon of blood.

Bats, however, are proven reservoirs and carriers of a variety of deadly animal viruses. Nocturnal attacks upon cattle ranches will often spread these blood-borne pathogens, thus decimating the herds of steer. The monetary loss, in Mexican herds particularly, has been considerable.

Bats are also proven vectors of human pathogens such as Venezuelan equine encephalitis and rabies. The dried droppings of bats can serve as the source of the airborne organisms causing histoplasmosis. The number of humans infected through the intermediacy of bats, however, remains small.

Bram Stoker's mother lived to witness the astonishing fame generated by her son's 1897 gothic novel. His chilling book lives on in films, in the legitimate theater, as a novel in uncounted languages - and in the image of Dracula's face when Halloween masks are annually retrieved. And Bram Stoker, the creator of Count Dracula? He died in 1912 of that most pedestrian, most unspectral disease of the Edwardian era: tertiary syphilis.

— Stanley M. Aronson, MD



Brown University AIDS Program

PRIMARY PROVIDER AIDS EDUCATION PROGRAM

March 4 & 11, 5:30 - 9:00 pm

The Brown University AIDS Program, with the assistance of the New England AIDS Education and Training Center, is sponsoring a two-part program to train primary care providers in issues surrounding AIDS and Human Immunodeficiency Virus (HIV) infection. Our goal is to facilitate comfort in the evaluation and management of individuals with HIV infection, and to increase knowledge of resources available for appropriate triage.

Topics to be covered on March 4 include:

- Recognizing and Monitoring HIV Infection
- Infection Control Practices
(One hour blood borne pathogen CME offered)
- Current Treatment Recommendations
- Strategies for HIV Prevention

Topics to be covered on March 11 include:

- Antiretroviral Therapy Update
- Opportunistic Infection Management
- Psychosocial Impact of HIV Infection

Lectures will be followed by clinical case discussions.

* * *

This schedule is subject to change.
Seating is limited and registration is mandatory.
To register and obtain a final program
call: 401 863-1725 or email BRUNAP@brown.edu

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The Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

The Brown University School of Medicine designates this activity for a maximum of 6.0 hours in Category 1 of the Physician's Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Current Knowledge of the Cytochrome P-450 Isozyme System: Can We Predict Clinically Important Drug Interactions?

David S. McKindley, PharmD, and Robert L. Dufresne, PhD

Drug interactions during therapeutic management may lead to significant toxicity or treatment failures. One of the primary mechanisms for the development of interactions is a perturbation in one or multiple hepatic enzymes that make up the cytochrome P450 enzyme system. This complex family includes many subfamilies of enzymes; and researchers are rapidly discovering new enzymes in this family, which explain the increasing complexity of drug interactions involving cytochrome P450 enzymes.

Here we examine how new findings on drug interactions involving drugs metabolized via the cytochrome P450 enzyme system relate to practical pharmacotherapy. We discuss the ma-

ior interactions involving these systems. Knowledge of these systems can help predict clinically significant interactions. By no means is this review inclusive. Older drugs frequently involved in interactions are not discussed in depth, but are included in a table of substrates, inducers, and inhibitors of the cytochrome P450 enzyme system.

Cytochrome P-450 Enzyme System

The cytochrome P450 is a major family of enzymes located in the smooth endoplasmic reticulum of virtually all tissues, but present at highest concentrations in the liver.¹ At least 30 different enzymes within this family have been identified in humans.² However, there may be up to 200 enzymes that have not

been identified. A primary role of these isozymes is the hepatic metabolism of drug compounds, but they also play a role in the biosynthesis or catabolism of steroid hormones, bile acids, fat-soluble vitamins, fatty acids and eicosanoids.¹ The primary enzymes in the cytochrome P450 family that are involved with the metabolism of drugs are CYP1A2, CYP2C, CYP2D6, and CYP3A4. Any drug metabolized via one of these enzymes is called a substrate. Table 1 lists several substrates for each enzyme pathway. At present, the CYP2D6 isozyme is the only enzyme shown to be present at two significantly different concentrations in humans. Approximately 5-10% of the Caucasian population are deficient in this enzyme and hence unable to metabolize drugs (i.e., substrates) that are metabolized via the CYP2D6 isozyme.

Because the number of newly discovered isozymes is rapidly increasing, the knowledge of drug interactions involving this enzyme system is often outdated. Therefore, background knowledge of a drug and the specific enzyme pathway responsible for its metabolism may help predict the occurrence of clinically significant drug interactions before it is documented. In addition, information on whether the drug can adversely affect an enzyme pathway (i.e., inhibit or induce enzyme activity) will also help one anticipate potential drug interactions.

Cytochrome P450 Enzyme Inhibition and Induction

The cytochrome P450 enzyme system is divided into specific enzymes that are responsible for the metabolism of drugs. Some of these enzymes can be inhibited or induced by certain drugs that can adversely affect the metabolism of another drug, which may lead to clinically significant drug interactions.

Enzyme inhibition by drugs can be either competitive or noncompetitive.¹

Table 1. Drugs metabolized via the CYP450 enzyme system³
SUBSTRATES

1A2	2C	2D6	3A4
caffeine	carbamazepine	chlorpromazine	alprazolam
clarithromycin	diazepam	clozapine	amiodarone
clozapine	nifedipine	codeine	amlodipine
fluvoxamine	phenytoin	desipramine	astemizole
haloperidol	propranolol	dextromethorphan	carbamazepine
methadone	ritonavir	encainide	cisapride
ondansetron	sulfonamides	flecainide	chlorpromazine
propafenone	tolbutamide	fluoxetine	cyclosporine
ritonavir	TCA	fluphenazine	diazepam
theophylline	valproic acid	haloperidol	diltiazem
TCA	warfarin	imipramine	etoposide
verapamil		maprotiline	felodipine
		metoprolol	ketoconazole
		mexiletine	midazolam
		nortriptyline	nefazodone
		paroxetine	nicardipine
		perphenazine	nifedipine
		propafenone	nimodipine
		propranolol	propafenone
		quinidine	quinidine
		risperidone	ritonavir
		ritonavir	saquinavir
		thioridazine	sertraline
		timolol	terfenadine
		triazolam	theophylline
		TCA	triazolam
		venlafaxine	verapamil
		vinblastine	vinblastine

TCA: tricyclic antidepressants

Table 2. Significant inhibitors of the cytochrome P450 enzyme system³

INHIBITORS

1A2	2C	2D6	3A4
cimetidine	amiodarone	cimetidine	cimetidine
ciprofloxacin	cimetidine	fluoxetine	clarithromycin
enoxacin	disulfiram	haloperidol	diltiazem
fluvoxamine	fluconazole	methadone	erythromycin
mexiletine	fluoxetine	paroxetine	fluconazole
norfloxacin	fluvoxamine	perphenazine	fluoxetine
ticlopidine	ketoconazole	quinidine	fluvoxamine
	omeprazole	sertraline	indinavir
	ritonavir	thioridazine	itraconazole
	sertraline		ketoconazole
	sulfonamides		nefazodone
			nelfinavir
			nifedipine
			norfloxacin
			omeprazole
			paroxetine
			ritonavir
			saquinavir
			sertraline
			verapamil

The acute effect of both types of inhibition can produce clinically significant drug interactions; however, the noncompetitive inhibition produces permanent inhibition of those enzymes affected. This inhibition is overcome after new enzymes are produced. Table 2 lists examples of enzyme inhibitors. Specific clinically significant interactions involving some of these drugs will be discussed in the following sections.

Some cytochrome P450 enzymes are inducible, that is, compounds can produce increased synthesis of an enzyme leading to an increased rate of metabolism of other compounds metabolized via the induced enzyme pathway. Currently, those cytochrome P450 isozymes involved with drug metabolism that can be induced in humans include CYP1A2, CYP2C, and CYP3A4. Table 3 includes a list of drugs identified as cytochrome P450 enzyme inducers. Induction of cytochrome P450 enzymes may occur as early as 24 hours but may continue to produce induction up to several weeks after the administration of an inducing agent. Drug interactions involving enzyme inducers would lead to therapeutic failures rather than toxicity.

Knowledge of the cytochrome P450

enzymes responsible for the metabolism of specific drugs and those that produce significant enzyme inhibition and induction would aid the clinician in predicting or explaining drug interactions. Therefore, it is important to be familiar with the new agents that are likely to produce significant interactions.

Quinolone and Macrolide Antibiotics

Macrolide antibiotics (eg, erythromycin, clarithromycin) are examples of significant inhibitors of the CYP3A4 enzyme. Therefore, any drug in Table 1 that represents substrates for the CYP3A4 enzyme could lead to a significant drug interaction that will result in decreased metabolism of the substrate

and a resultant increase in the serum concentrations of that substrate. Examples of highly significant drug interactions involving the macrolides include the nonsedating antihistamines such as terfenadine and astemizole. A significant reduction in the clearance of these antihistamines leads to pronounced increases in the parent drug compound which has led to potentially fatal cardiac arrhythmias. When a macrolide and a nonsedating antihistamine is required, azithromycin should be used as the macrolide of choice because this agent does not produce significant inhibition of the CYP3A4 enzyme. Erythromycin and clarithromycin can also produce a significant drug interaction when administered with cisapride. Cisapride concentrations increase to a toxic level secondary to the enzyme inhibition leading to potentially fatal cardiac arrhythmias. As with the interaction involving the nonsedating antihistamines, azithromycin should be used in combination with cisapride if a macrolide antibiotic is required.

Frequently observed drug interactions between the quinolone antibiotics such as ciprofloxacin, enoxacin, or norfloxacin and theophylline or its salt aminophylline can lead to a significant increase in the concentrations of theophylline due to inhibition of its metabolism and subsequent toxicity. Erythromycin and clarithromycin can also reduce the clearance of theophylline to the point of producing toxicity.

Cimetidine

Cimetidine can produce significant inhibition of each of the major classes of drug metabolizing enzymes (CYP1A2, CYP2C, CYP2D6, and CYP3A4). Its use is a concern in many patients because

Table 3. Significant inducers of the cytochrome P450 enzyme system³

INDUCERS

1A2	2C	2D6	3A4
barbiturates	barbiturates	none identified	barbiturates
charbroiled food	rifampin		carbamazepine
cigarette smoke			phenytoin
omeprazole			rifabutin
phenytoin			rifampin

cimetidine is now available over-the-counter. There are 26 clinically significant drug interactions that involve cimetidine, including those that are well documented moderate to severe interactions.³ Therefore, patients should understand the potential for interactions.

Examples of clinically significant drug interactions with cimetidine include theophylline, aminophylline, metoprolol, propranolol, moricizine, nifedipine, and quinidine. The interaction between theophylline and cimetidine may occur within 24 hours after initiating cimetidine with a maximum effect observed by 72 hours.³ Theophylline clearance is reduced by 33-50% and has resulted in theophylline induced seizures. A similar interaction would be expected with aminophylline. The interaction involving the β -blockers metoprolol and propranolol results in significant sinus bradycardia and decreases in blood pressure. If β -blocker therapy is required, the hemodynamic status of the patient should be closely monitored. These

agents can safely be administered together as long as dosage adjustments are made if pronounced β -blocker effects are observed. The β -blockers atenolol and nadolol have not been shown to interact with cimetidine.

Azole Antifungals

The azole antifungal agents involved in clinically significant drug interactions include fluconazole, itraconazole, and ketoconazole. They can produce significant inhibition of the CYP2C and CYP3A4 enzymes. Those substrates that are metabolized via these enzymes and lead to moderate to severe drug interactions with the azole antifungals are phenytoin, warfarin, cisapride, and cyclosporine. The interaction involving phenytoin has only been described when combined with fluconazole. Phenytoin concentrations were significantly increased 48 hours after fluconazole administration resulting from a 33% decrease in the clearance of phenytoin.⁴ This interaction does not appear to

occur between ketoconazole and phenytoin. Concomitant administration of the azole antifungals and cisapride is contraindicated because of the decreased metabolism of cisapride leading to elevated concentrations. High concentrations of cisapride can produce potentially life-threatening cardiac arrhythmias. When these antifungals are administered together with cyclosporin the concentrations of cyclosporin are increased. Frequent monitoring of cyclosporin concentrations and adjustment of the dosage are required to avoid serious side effects. Likewise, frequent monitoring (every two days) of the prothrombin time is required when an azole antifungal agent is added to or discontinued from warfarin therapy.

Protease Inhibitors

A relatively new class of drugs, protease inhibitors, are used in the routine treatment of HIV patients.⁵ This group of agents, which include ritonavir (Novir[®]), saquinavir (Invirase[®]), indinavir (Crixivan[®]), and nelfinavir (Viracept[®]), are all inhibitors of the CYP3A4 isozyme,⁵ while ritonavir also appears to inhibit the CYP2D6 isozyme.⁶ The enzyme inhibition produced by saquinavir does not appear to be significant and, therefore, concomitant administration with other drugs is not contraindicated by the manufacturer. Ritonavir may also induce CYP3A4 and CYP1A2 isozymes leading to autoinduction of its own metabolism and that of other agents like theophylline.⁶ Any drug metabolized through the CYP3A4 pathway (Table 1) could potentially interact with any of these protease inhibitors leading to significant increases in the serum concentrations of those drugs added to a protease inhibitor regimen. Likewise, a number of those drugs that induce the CYP3A4 isozyme (Table 3) could lead to decreases in the serum concentrations of the protease inhibitors. A list of those drug interactions involving protease inhibitors that are clinically significant are described in Table 4.

Psychotropic Agents

While some psychotropic drugs such as lithium are eliminated almost entirely by renal mechanisms, many require extensive hepatic metabolism. A knowledge of CYP450 systems can highlight not only potential interactions between known

Table 4. Drugs that are contraindicated by the drug manufacturer and should not be coadministered with the protease inhibitors^{5,6}

Interacting Drug	Primary Drug	Resultant Effect on the Clearance of Primary Drug
Ritonavir	Nonsedating antihistamines astemizole, terfenadine	Decrease
	Cisapride	Decrease
	Amiodarone	Decrease
	Encainide, Flecainide	Decrease
	Quinidine	Decrease
	Benzodiazepines alprazolam, clorazepate, diazepam, flurazepam, midazolam, triazolam	Decrease
	Rifabutin	Decrease
	Bepridil	Decrease
	Bupropion	Decrease
	Clozapine	Decrease
	Meperidine	Decrease
	Piroxicam	Decrease
	Propafenone	Decrease
	Propoxyphene	Decrease
Indinavir	Nonsedating antihistamines astemizole, terfenadine	Decrease
	Cisapride	Decrease
	Midazolam, Triazolam	Decrease
Nelfinavir	Nonsedating antihistamines astemizole, terfenadine	Decrease
	Cisapride	Decrease
	Rifampin	Increase
	Midazolam, Triazolam	Decrease

medications, but also possible future interactions with other new medications prior to there being extensive experience with them. Not every potential interaction, however, will be clinically significant.

Even patients who are taking only one prescription medication may need to be warned about a potential drug interaction. For example, patients taking fluvoxamine for obsessive compulsive disorder may notice an increase in anxiety or insomnia if they consume even moderate amounts of caffeine (eg, coffee, soda) as the metabolism of caffeine will be impaired via inhibition of CYP1A2. While far from lethal, such an interaction could worsen a patient's condition, convincing him to abandon a potentially useful treatment. An interaction has been reported with the selective serotonin reuptake inhibitor antidepressant fluoxetine (i.e., potent CYP2D6 inhibitor) and dextromethorphan (i.e., CYP2D6 substrate; Table 1). This interaction may elevate blood concentrations of dextromethorphan, again worsening a patient's status, and causing the clinician to give up on fluoxetine prior to providing an adequate trial of the medication.

Because patients often take more than one psychiatric medication, the therapeutic or adverse reaction to a second augmenting medication may result from a pharmacokinetic rather than a pharmacodynamic effect.⁷ For example, a patient receiving the noradrenergic antidepressant desipramine may have treatment augmented with a serotonergic agent such as fluoxetine. While their mechanisms of action may differ, the increase in desipramine levels via the inhibition of CYP2D6 may cause either the beneficial or untoward effect.

Inhibition of the CYP3A4 isozyme can alter the metabolism of many psychotropic drugs. Nefazodone and fluoxetine (via its metabolite norfluoxetine) are moderately potent CYP3A4 inhibitors, while fluvoxamine and sertraline do the same to a lesser extent.⁸ While these drugs are not as potent at inhibiting the CYP3A4 system as ketoconazole, itraconazole, or the macrolide antibiotics, the possibility for interactions exists; and these antidepressants must be used with caution when used with other CYP3A4 substrates. For example, an increase in cyclosporine levels to 167% of baseline was seen in a patient started on nefazodone.⁹ Other potential interactions with nefazodone via this mechanism in-

volve increasing serum levels of alprazolam, triazolam, terfenadine, and astemizole while fluvoxamine, sertraline, and fluoxetine produce increased serum levels of carbamazepine by this mechanism. Cisapride levels have also been increased by the CYP3A4 inhibiting effects of nefazodone; like the effect with terfenadine or astemizole, this interaction may cause QT prolongation with the possibility of ventricular arrhythmias. The inhibition of these enzymes is dose dependent and may manifest itself in patients only with a higher dosage of the antidepressant. So while often only a dosage adjustment may be necessary, the possibility for drug interactions of this type exists with these medications.

*... background
knowledge of a drug and
the specific enzyme
pathway responsible for
its metabolism may help
predict the occurrence of
clinically significant drug
interactions before it is
documented.*



The introduction of protease inhibitors for the treatment of HIV has introduced the potential for interactions with many psychotropic medications which are metabolized via the CYP3A isozyme system due to the strong inhibition of the CYP3A4 isozyme. Examples of key psychotherapeutic agents metabolized via CYP3A4 include carbamazepine, clomipramine, alprazolam, triazolam, and midazolam. Clinicians should be aware of the potential for increased levels of these psychotherapeutic agents when a protease inhibitor is introduced.

Induction of the CYP3A4 isozyme can also result in important interactions. For example, in one study the addition of rifampin to a triazolam regimen caused an approximately ten-fold reduction in serum triazolam; this rendered the therapy ineffective.¹⁰ It is unknown if the loss of therapeutic efficacy of other psychotropic medications metabolized by the CYP3A4

system such as alprazolam, midazolam, and carbamazepine could occur via the same mechanism.

Many important drug interactions between psychotherapeutic and concomitant agents occur via the CYP2D6 isozyme system. The small percentage of Caucasians who lack this isozyme may experience an exaggerated response and adverse effects from smaller than typical dosages of those medications metabolized via the CYP2D6 isozyme. Psychotherapeutic agents which are heavily metabolized via the CYP2D6 isozyme system include the antidepressants nortriptyline, desipramine, imipramine, venlafaxine, fluoxetine and paroxetine; and the antipsychotics haloperidol, perphenazine, clozapine, risperidone, and thioridazine. Psychotherapeutic agents which are significant inhibitors of these agents include antidepressants such as sertraline, paroxetine and fluoxetine.

A potentially serious interaction that can occur via the CYP2C isozyme is the inhibition of the metabolism of phenytoin via the concurrent administration of fluoxetine. In 23 cases fluoxetine caused plasma levels of phenytoin to rise an average of 161% over baseline.¹¹ Clearly this is a potentially serious interaction; it may be best to avoid this combination whenever possible and to monitor phenytoin levels closely when it must be used. Of lesser importance but worth noting is the potential interaction between fluoxetine, fluvoxamine, and sertraline with diazepam via another CYP2C isozyme subsystem. In one study with normal volunteers fluvoxamine doubled the half-life of diazepam and also increased that of the active metabolite n-desmethyldiazepam.¹² In another study with healthy volunteers fluoxetine caused an increased half-life of a single dose of diazepam by decreasing its clearance.¹³

Drug interactions involving the cytochrome CYP1A2 subsystem are of concern when adding fluvoxamine to a regimen. Even when using fluvoxamine alone, one must be concerned about the ability of fluvoxamine to increase levels of caffeine by increasing its half-life from 5 to 31 hours¹⁴ in a patient population clearly vulnerable to the anxiety-producing effect of this common drug. A similar interaction can occur in which fluvoxamine can increase theophylline levels dramatically. Clozapine and tacrine are

two notable examples of other drugs whose levels can also be increased via this mechanism.

Drug Interactions Involving Enzyme Induction

While interactions involving the induction of drug metabolism are typically not as severe as those involving metabolism inhibition, they may lead to subtherapeutic blood concentrations and subsequent therapeutic failure.

Well known drugs that produce significant enzyme induction include the barbiturates and rifampin. Additional enzyme inducers are listed in Table 3. The barbiturates which primarily include phenobarbital and pentobarbital induce the enzyme activity of CYP1A2, CYP2C, and CYP3A4. There are 39 drug interactions involving the barbiturates and 55 interactions involving rifampin that are classified as producing well documented moderate to severe interactions.³ One noteworthy interaction with the barbiturates is that of warfarin resulting in decreased warfarin effectiveness secondary to increased metabolism. Careful monitoring of the prothrombin time is essential not only when barbiturates are added to a warfarin regimen but also when barbiturates are discontinued after a patient is stabilized on the two drugs. The latter has resulted in significantly increased numbers of bleeding episodes.

The same mechanism that produces the interaction between barbiturates and warfarin is responsible for the interaction between rifampin and warfarin. One case report demonstrated that the warfarin dose had to be increased by 50% to maintain therapeutic effects of warfarin.¹⁵ Another important drug interaction that occurs with rifampin is cyclosporin. This interaction can be apparent within 48 hours of adding rifampin to a regimen of cyclosporin where cyclosporine concentrations are significantly reduced and can continue for up to 1-3 weeks following the discontinuation of rifampin.³ Organ rejection following transplantation¹⁶ as well as one fatality have been reported secondary to a significant reduction in cyclosporine concentrations following rifampin therapy. This drug combination can be managed without discontinuation of rifampin therapy as long as

the clinician aggressively monitors the blood concentrations of cyclosporin anticipating significant reductions in its concentration.

Conclusion

Drug interactions involving the cytochrome P450 system are possible when therapeutic regimens include any of the agents listed in Tables 1-3. Many of these drugs are prescribed in patients who could be considered "high-risk" for drug interactions - i.e., patients who have cardiovascular diseases, infections, gastrointestinal diseases, and psychiatric diseases.

Prediction of interactions is possible when one recognizes which agents are likely to produce drug metabolism alterations through inhibition or induction of the cytochrome P450 system. Many of these drug combinations, however, can be administered safely with appropriate dosage adjustments.

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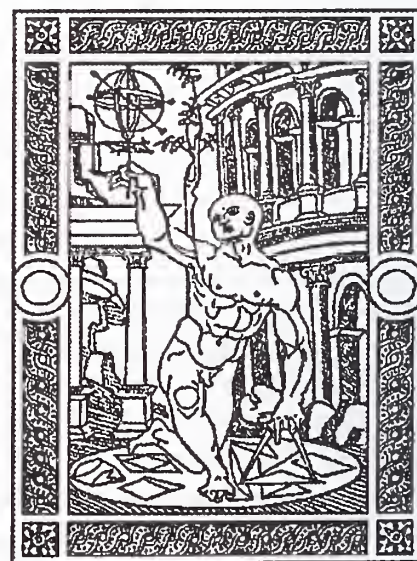
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Alternative Medicines:

Pharmacologic and Professional Issues

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Alternative medicine is a term used in the United States to describe remedies and techniques which are scientifically unproven in the prevention or treatment of disease.¹ Some practices, known for centuries, are documented in literature from ancient Greece, Italy, China, India and other Eastern countries. Those frequently chosen by patients include acupuncture, herbal therapy, meditation, massage, biofeedback, hyperthermia, diet, and chiropractic treatment. Other widely used practices such as aromatherapy, Ayurveda, and Traditional Chinese Medicine (TCM) combine herbal therapy with spiritual and mind restoration techniques (Table I). Recently there has been a dramatic increase in the use of alternative medicine. The reasons are multiple and include:

- 1) immigration into the United States;
- 2) advertising and promotion through the media and Internet;
- 3) new legislation facilitating consumer access.

Practitioners of conventional medicine can no longer deny that alternative medicine often influences patient care. Managed care organizations now reimburse some alternative medicine practices. Washington State requires insurers to cover many alternative medicine therapies. In New England, Harvard Pilgrim Health Care pays for chiropractic treatments.²

A 1993 telephone interview by investigators from Harvard Medical School evaluated the prevalence, costs, and use of alternative medicine therapies in 1,539 adults: the frequency of use for at least one alternative medicine therapy was 34%. Among the conditions studied, the disease or

symptoms for which most patients frequently sought alternative medicine treatment were back problems (36%), anxiety (28%), headaches (27%), chronic pain (26%), and cancer or tumors (24%). A majority of respondents (55%) paid for all costs of the alternative medicine therapy. In 1990, an estimated \$10.3 billion dollars in expenses were paid out of pocket by patients. Third party payment was most common for herbal therapy (83%), biofeedback (40%), chiropractors (39%) and vitamins (30%).³

The popularity of herbal therapy and minimal government regulation have created a situation where consumer utilization has increased despite the lack of scientific evidence on safety and efficacy. This article will discuss the current use of herbal products.

Abbreviations Used:

DSHE	Dietary Supplement Health and Education Act
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act of 1938
GMP	Good Manufacturing Practices
GRAS	generally regarded as safe
NCI	National Cancer Institute
PL	public law
SLE	systemic lupus erythematosis
TCM	Traditional Chinese Medicine

DEFINITIONS OF TERMS USED IN ALTERNATIVE MEDICINE

"Quackery" is the promotion of an unproven product or service with the intent of deceiving the consumer. "Fraudulent intent" separates quackery from alternative medicine practices.¹ Laetrile (amygdalin) is an example of "anti-cancer" drug, derived from apricot pits, that was exploited to the public. Because it was not approved by the Food and Drug Administration (FDA) for use in the United States, patients flocked to Mexican border

Table 1. Alternative medicine practices that incorporate herbal therapy.

PRACTICE	DEFINITION
Aromatherapy <i>Origin: Egypt, India, Italy, China</i>	Use of essential oils extracted from plants and herbs to treat infections, skin disorders, immune deficiencies, and stress
Ayurveda <i>Origin: India</i>	Management of disease or bodily imbalance through cleansing and detoxifying, palliation, rejuvenation, and mental healing with diet, exercise, meditation, herbs, massage, sun, and breathing
Herbal Medicine <i>Origin: Universal</i>	Most ancient form of health care utilizing the root, bark, stem, leaves and flowers of plants, trees, and shrubs for prevention and treatment of disease
Traditional Chinese Medicine <i>Origin: China</i>	Combines herbs, acupuncture, food therapy, massage, and exercise in a preventative medicine strategy to circumvent disease

Table 2. Summary of FDA regulations for drug products.

DATE	REGULATION	PURPOSE
1938	Food, Drug and Cosmetics Act [21 U.S.C. 321]	Defined a "drug" and established guidelines for marketing, packaging, and labeling; mandated safety testing
1962	Kefauver-Harris Amendment [P.L. 87-781]	Efficacy and safety testing
1990	Omnibus Budget Reconciliation Act [P.L. 101-508]	Mandated patient counseling on new prescriptions for Medicaid patients
1994	Dietary Supplement and Health Education Act [P.L. 103-417]	Permits limited therapeutic claims without efficacy studies; Good Manufacturing Practices not required

clinics seeking the compound. Growing public interest in laetrile in this country resulted in a clinical trial supported by the National Cancer Institute (NCI) which showed that the drug had no effect on cancer.⁴

The term "nutraceutical" is frequently used in alternative medicine. Dr. Stephen DeFelice, Chairman of the Foundation for Innovation in Medicine, coined the term in 1990 to cover many of the preparations and products used in alternative medicine. A nutraceutical is defined as, "any substance that may be considered food or part of a food and provides medical or health benefits, including the prevention and treatment of disease." It includes medical foods and dietary supplements.⁵

A "medical food" is a specific term, codified in a 1988 amendment to the Orphan Drug Act. It is defined as a product "formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". Infant feeding formulas are an example.⁶

"Dietary supplement" can refer to vitamins, minerals, trace elements, amino acids, botanical products, and dubious substances such as bioflavonoids and shark cartilage. As

a result of the Dietary Supplement Health and Education Act (DSHE) of 1994, ingredients in dietary supplements are no longer considered to be food additives, which means they do not have to necessarily have GRAS (generally regarded as safe) status in order to be marketed.⁷ The definition is confusing because "botanical products" are derived from plants and can be used as food or medicine. However, the therapeutic claim associated with a botanical derivative determines how the product will be used in alternative medicine.

LEGAL ISSUES

The federal Food, Drug, and Cosmetic Act of 1938 (FDCA) defined the term "drug" and set the initial guidelines for marketing, packaging, and labeling of pharmaceuticals. The act defined a drug as "... articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals other than food" and "intended to affect the structure or any function of the body of man or other animals". [21 U.S. Code 321 (g)(1)] From the enforcement perspective, drugs and products (i.e. - "articles") making claims within the definition above but failing to meet FDA review and approval criteria would be illegally marketed. However, Congress expanded a special category for dietary supplements with the passage of the DSHE act of 1994. [P.L.

103-417] Because of this legislation, dietary supplements can now advertise and promote claims that are similar to a "drug" but do not require FDA approval. To further complicate this issue, dietary supplements may be formulated in a facility which does not meet current Good Manufacturing Practices (GMP), standards that are required for manufacturers of drug products. (Table 2)

The standardization of products used in alternative medicine practices is a major issue in this country. Several forms of "adulteration" (i.e. - to make impure by the addition of an inferior ingredient or alteration of strength and quality) occur. For example, some commercial products which use expensive starting materials, such as ginseng and ginkgo biloba, contain very little of the active ingredients, ginsenosides or ginkgonolides. Another common practice seen with imported crude preparations is the addition of potentially deleterious substances such as caffeine or phenylbutazone. According to the DSHE act of 1994, a dietary supplement may be deemed adulterated if it "presents unreasonable risk or illness or injury". Ironically, however, the burden of proof lies with the FDA.

CURRENT USE OF HERBAL PRODUCTS

The growing popularity of herbal therapy has expanded the consumer market for nonprescription botanical products (tablets, capsules, teas, lotions, balms, extracts, and aromatic oils). This trend is not only due to the influx of immigrants, but also to speculative importation and marketing of exotic health and healing products. Almost all the crude plant products (i.e., raw or natural form) and their extracts listed in the U.S. Dispensatory at the turn of the century are now found in supermarkets, pharmacies, and health food stores. The 10 most commonly purchased herbal products (representing 57% of sales) in the United States according to the October 1997 issue of Whole Foods catalog are echinacea, garlic, ginkgo, goldenseal, saw palmetto, aloe, ginseng,

Table 3. Common herbs used in alternative medicine.

HERB	MARKETED USE	CONTRAINDICATIONS
Aloe (<i>Aloe vera</i>)	<u>Oral</u> : constipation <u>Topical</u> : soften skin and promote healing	Oral: pregnancy & lactation
Astragalus (<i>Astragalus membranaceus</i>)	<u>Oral</u> : stimulates immune system against infections	Unknown
Cayenne (<i>Capsicum annuum</i>)	<u>Oral</u> : stimulate blood flow; relief of gas, dyspepsia, and colic <u>Topical</u> : analgesia	None
Cat's Claw (<i>Uncaria tomentosa</i>)	<u>Oral</u> : stimulate the immune system and reduce inflammation	Unknown
Chamomile (<i>Matricaria recutita</i>)	<u>Oral</u> : gas, dyspepsia, colic, anxiety, tension, and muscle spasms <u>Topical</u> : reduce skin and mucosal inflammation	Unknown
Echinacea (<i>Echinacea angustifolia</i>)	<u>Oral</u> : stimulates immune system against infections <u>Topical</u> : reduce inflammation and promote wound healing	Unknown
Garlic (<i>Allium sativum</i>)	<u>Oral</u> : relief of symptoms from colds, flu, and respiratory infections; reduce blood lipids and pressure	None
Ginkgo (<i>Ginkgo biloba</i>)	<u>Oral</u> : improve peripheral blood circulation, hearing, memory, anxiety, and headaches	Unknown
Ginseng (<i>Panax ginseng</i>)	<u>Oral</u> : relieve stress and increase body stamina	Acute inflammatory diseases
Goldenseal (<i>Hydrastis canadensis</i>)	<u>Oral</u> : peptic ulcers and colitis <u>Topical</u> : reduce inflammation of skin and mucus membranes	Pregnancy
Peppermint (<i>Mentha piperita</i>)	<u>Oral</u> : gastrointestinal spasms and cramps, gas, and irritable bowel <u>Topical</u> : analgesic	None
St. John's Wort (<i>Hypericum perforatum</i>)	<u>Oral</u> : decrease anxiety, tension, and mild depression <u>Topical</u> : promote healing of wounds and mild burns	Unknown
Saw Palmetto (<i>Serenoa repens</i>)	<u>Oral</u> : relieve symptoms of benign prostatic hypertrophy (enlarged prostate in males)	Unknown
Senna (<i>Cassia angustifolia</i>)	<u>Oral</u> : constipation	Pregnancy and lactation unless under the advise of a medical physician
Valerian (<i>Valeriana officinalis</i>)	<u>Oral</u> : sedative used to induce sleep; relief of cramps and intestinal colic	Unknown
Witch hazel (<i>Hamamelis virginiana</i>)	<u>Topical</u> : Soothe hemorrhoids, bruises, and swelling	Unknown

cat's claw, astragalus, and cayenne.⁹ Other popular products include St. John's wort, valerian, chamomile, senna, peppermint, and witch hazel (Table 3).

Many of the marketed uses for these herbal products have not been

proven through clinical trials. However, published data on the benefits of some herbs should be recognized. Garlic is universally known for its culinary and medicinal uses. In 1993, a meta-analysis of clinical trials identified through the MEDLINE data-

base assessed the effect of garlic on the size and consistency of total cholesterol reduction. The study concluded that garlic consumption of one-half to one clove per day can decrease total serum cholesterol levels by as much as 9%.¹⁰

Traditional Chinese Medicine (TCM) has bolstered sales of herbal products in the United States. Many products sold are single, herbal ingredients such as dong quai, glycyrrhiza, ephedra, and ginseng. Some of the herbs used in different cultures are associated with a religious or mystical purpose. Herbs with a spiritual significance that are esteemed in ethnic groups can complicate the provision of conventional medicine.

The efficacy of most traditional medicine herbs is unsubstantiated despite extensive study. In the case of Chinese and other Asian traditional medicine, the matter is further complicated by the fact that the regimens contain multi-ingredients, and are claimed to be effective only in concerted manners. For example, in TCM ginseng may be combined with astragalus to reduce the arteriole constriction caused by the ginsenosides.

Above all, public safety should be the major concern in determining the value of an alternative practice. Most of the herbal therapies have not been studied for teratogenicity or adverse effects to pregnant and lactating women. Since the dangers from some of these herbs are not always evident, they should be avoided during pregnancy unless under the advice of a physician. Goldenseal, for example, is marketed for treatment of dyspepsia and other gastrointestinal ailments which many pregnant women experience. But goldenseal causes contractions and can induce labor.

There are many other examples of toxicities and adverse effects associated with herbal medicines.¹¹ Comfrey, an alleged cure-all health plant, contains pyrrolizidine alkaloids which are known to be hepatotoxic and carcinogenic. Alfalfa, available as sprouts, dried leaves, and seeds, contains a large amount of canavanine (an arginine competitor), which may enhance the disease symptoms of systemic lupus erythematosis (SLE). Glycyrrhizin in glycyrrhiza (licorice root) is an inhibitor of metabolism for aldosterone and other corticoids, which can increase sodium levels. Ephedra, the key ingredient in "ecstasy" drugs, can

raise the blood pressure to dangerous levels. The "potential danger to human health" associated with some alternative medicines has sparked controversy over government regulation, practice standards, and product safety testing.

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PROFESSIONAL ISSUES

One of the biggest problems in the United States regarding alternative medicine is that patients are misinformed about the benefits and hazards of the different therapies. For example, Ayurvedic treatment requires cleansing and detoxifying the body with herbal concoctions, including the administration of small amounts of toxic substances (i.e. - lead, mercury, or arsenic). Reports indicate that liver and kidney damage have resulted from Ayurvedic herbal mixtures. In several cases, the toxicity was secondary to patients using more of the herbal mixture than recommended.^{12,13}

St. John's wort's impact on depression was featured on ABC's prime-time "20/20" last June. Although the commentators warned viewers not to throw out their prescription antidepressants without the advice of a physician, the patient testimonials for St. John's wort convinced many viewers that this was an herbal version of Prozac (fluoxetine). Yet St. John's wort has only been used in cases of mild depression and it may take 3-6 weeks for any effect to be noticed. Also, prolonged

use or high doses can make the skin more sensitive to sunlight. A joint collaboration of the National Institute of Health's Office of Alternative Medicine, the National Institute of Mental Health, and the Office of Dietary Supplements is now funding research to investigate the efficacy of St. John's wort.

In 1995, the National Institutes of Health Office of Alternative Medicine received several recommendations from an expert panel that evaluated the role of clinical practice guidelines for alternative medicine. The major points include:¹⁴

- 1) Practice guidelines should be evidence-based and not advocated solely on the basis of opinions pertaining to effectiveness.
- 2) Current evidence on alternative medicine therapies is inadequate to produce practice guidelines. Well-designed clinical trials are needed to provide data on safety and efficacy.
- 3) Alternative medicine practices should be included among treatment options considered by groups that develop practice guidelines in conventional medicine.
- 4) The Office of Alternative Medicine in conjunction with the National Library of Medicine should explore the possibility of providing online access to a MEDLARS database devoted to scientific literature in alternative medicine.
- 5) Consumer information should be made available through a government clearinghouse capable of integrating public education resources from different agencies and private groups.

Furthermore, standards for evaluating and credentialing the competency of alternative medicine practitioners should be promoted, but independent of the practice guidelines. Development of evidence-based practice guide-

lines will evolve over many years as the results from clinical research become available.

Because patients may not always use reliable information and good judgment to determine their treatment, physicians need to discuss options that include both conventional and alternative medicine therapies. Dr. David Eisenberg of Beth Israel Deaconess Medical Center in Boston describes the steps involved in addressing alternative medicine, including herbal therapy, with a patient. Dr. Eisenberg advises that a detailed discussion about alternative medicine should not occur until the patient has undergone a complete medical evaluation and tried or exhausted conventional therapeutic options. Then, the following approach can be used to discuss alternative medicine:

- 1) Ask the patient to identify the principal symptom.
- 2) Encourage the patient to maintain a symptom diary on a daily basis.
- 3) Discuss the patient's alternative medicine preferences and expectations.
- 4) Review the safety and efficacy associated with alternative medicine.
- 5) Identify a suitable, licensed provider.
- 6) Provide key questions to the patient to ask the alternative medicine provider during the initial consult.
- 7) Schedule a follow-up visit or telephone call after the initial visit to the alternative provider to review the treatment plan.
- 8) Follow the patient's response to the alternative medicine treatment.
- 9) Document all conversations and outcomes to build a record.

Many sources provide information on herbal therapies to both patients and physicians. Caution should

be taken when using the Internet because the information is not always current nor peer reviewed. Dr. Eisenberg provides a summary of addresses and Internet web sites for alternative medicine organizations.¹⁵

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⌘ Aging of the Population: Impact Upon Therapeutic Choices ⌘

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By the year 2030 more than 64 million people will be over age 65, constituting at least 21% of the population.¹ This article seeks to familiarize readers with the effects of aging on drug pharmacokinetics and pharmacodynamics, to review the epidemiology of adverse drug events in the elderly, and to provide practical guidelines for prescribing to this population.

AGE-ASSOCIATED CHANGES IN DRUG PHARMACOKINETICS AND PHARMACODYNAMICS

Important and sometimes subtle physiologic changes occur with normal aging - changes independent of the more apparent and multiple disease states prevalent in the elderly. Although age-related changes might be expected to alter drug response by influencing pharmacokinetics, differences in drug effect are multifactorial and influenced by environmental, genetic, physiological and pathological factors.

DRUG ABSORPTION

Although aging brings several changes in gastrointestinal tract function (increased gastric pH, decreased gastric-emptying, impaired intestinal motility, and diminished splanchnic circulation), these alone generally do not alter drug absorption in a clinically significant way.² One example in which these changes do affect drug absorption involves ketoconazole, which requires an acidic pH for absorption. Due to the increase in gastric pH that occurs with normal aging, the absorption of this drug can be decreased, potentially leading to ineffective therapy. However, alternative agents are available that are not affected by the change in pH (i.e., fluconazole, itraconazole).

Age-related physiologic changes may not have a large effect on drug absorption; however, co-existing diseases such as congestive heart failure may reduce the rate and extent of absorption.² Congestive heart failure (CHF) can reduce GI blood flow to a greater degree than normally occurs with aging. Impaired absorption of hydrochlorothiazide, metolazone, quinidine, and procainamide has occurred in patients with concomitant CHF.²

Combinations of drugs may result in impaired drug absorption. For example, cholestyramine will bind acidic drugs such as aspirin, penicillin, oral anticoagulants, cardiac glycosides, and thyroid preparations. This could decrease the effectiveness of the acidic drug (i.e., an unexpectedly low INR in a patient who had been previously therapeutic on warfarin). Aluminum, magnesium and calcium-containing antacids bind to form nonabsorbable complexes with certain medications, which may reduce or prevent their absorption. Examples of these drugs include tetracycline, quinolones, isoniazid, and iron.²

When drugs are administered with food, the possibility of drug-food interactions may impair drug absorption or bioavailability; tea and orange juice, respectively, decrease and increase the absorption of iron; acidic fruit juices and carbonated beverages inactivate many acid-labile drugs such as penicillin; and mineral oil-containing laxatives cause malabsorption of fat-soluble vitamins. The absorption of alendronate can be decreased substantially when it is taken with food, resulting in ineffective therapy. Thus,

Abbreviations Used:

CHF	congestive heart failure
CNS	central nervous system
INR	international normalized ratio
NSAID	nonsteroidal anti-inflammatory drug

drug-drug interactions and drug-food interactions probably influence drug absorption more than aging alone.

DISTRIBUTION

While considerable individual variation occurs, aging is accompanied by reductions in total and lean body mass, reduced total body water, and relatively increased adipose tissue mass. This proportional increase in adipose tissue mass increases the volume of distribution for lipid-soluble drugs such as diazepam, chlordiazepoxide, and flurazepam. In the elderly, these drugs will remain in the body longer. With repeated administration they can cause unwanted daytime sedation, dizziness and falls.³

Many drugs are bound to plasma proteins, which include albumin and alpha-1-acid glycoprotein. Plasma protein binding is considered significant when greater than 90% of the drug is bound, leaving 10% unbound and available for pharmacological effect. Several factors influence protein binding and are particularly important in the elderly: protein concentrations, concomitant disease states, coadministration of other drugs, and nutritional status.²

Basic drugs such as lidocaine and propranolol have a high binding affinity for alpha-1-acid glycoprotein. The concentration of this protein increases in response to inflammatory disorders. It is unclear if the increase of this protein in the elderly is a normal part of

aging. However, the potential exists for an increase in the protein binding of these basic drugs and a decrease in the concentration of unbound, active drug.²

Albumin is a major site for drug binding. Albumin concentrations may decrease with increasing age, as well as during an acute illness. Acidic drugs, such as phenytoin and diazepam, tend to bind to albumin. A decrease in albumin could increase the unbound concentration of these acidic drugs. In the frail elderly with multiple chronic diseases and poor nutritional status, larger declines in albumin concentrations could result in clinically important increases in unbound phenytoin concentrations. The measurement of the plasma free-drug concentration is a better guide to dose requirements than the total concentration, especially for drugs such as phenytoin, with a low therapeutic ratio.²

In general, changes in plasma protein binding alone do not result in significant changes in drug effect. Other factors, such as concurrent illness or concomitant medications that interfere with drug metabolism, must also be present before a significant effect can occur.

DRUG METABOLISM

The clearance of drugs by the liver depends on the enzymes responsible for biotransformation and on hepatic blood flow, which determines the rate of delivery of the drugs to the liver. With advancing age, hepatic cell mass declines and is accompanied by reduced hepatic blood flow, caused in part by a decline in cardiac output.²

A biochemical approach to hepatic metabolism relies on the classification of the biotransformation reactions into either phase 1 (oxidation, reduction, and hydrolysis), or phase 2 (glucuronidation, acetylation, and sulfation). In general, the capacity of phase 1 reactions is decreased to a greater extent than phase 2 reactions.

Long-acting benzodiazepines (chlor-diazepoxide, diazepam, flurazepam) undergo both phase 1 and 2 metabolism and have prolonged elimination in the elderly. This may cause oversedation, confusion, or ataxia. The rate of elimination of oxazepam, lorazepam, and temazepam as a result of phase 2 conjugation reactions is unaltered in the elderly. Therefore, cumulative or prolonged sedative effects are less likely.²

Hepatic drug metabolism is influenced by concurrent illness, nutritional status, gender, genetics, environmental factors, and concomitant medications. Recent studies have identified at least 12 isozyme families in the cytochrome P450 system.⁴ Since the elderly are commonly prescribed medications, knowing the specific isozyme by which a given drug is metabolized can help prevent drug interactions. For example, if an elderly patient with gastroesophageal reflux disease was taking cisapride, the concomitant use of terfenadine for allergies should be avoided. Cisapride can inhibit the metabolism of terfenadine and arrhythmias may result. (See the article by McKindley and Dufresne, this is-

sue).

RENAL ELIMINATION

Renal function declines with age. In contrast with the liver, where the decline in drug metabolizing activity is not reflected in liver function tests, age-related changes in renal function are more predictable and are reflected in serum creatinine values. Age-related changes in renal function include a reduction in the number of functioning nephrons, reduced renal plasma flow, reduced glomerular filtration rate and impaired renal tubular secretion. Normal creatinine clearance has decreased by an average of 30%-40% by the age of 80.² Pathological conditions (diabetes, hypertension, and congestive heart failure) can further reduce creatinine clearance and also compound age-related loss of renal function. In the elderly it should be assumed that some degree of renal impairment is present even when serum creatinine is within the normal range. Endogenous creatinine clearance may be calculated from serum and urine values or predicted from the equation of Cockcroft and Gault.⁵ In men the creatinine clearance is estimated as:

TABLE 1. Examples of drugs cleared by the kidney which require dosage adjustment in the elderly ^{16,17}

CLASS	DRUG
ACE inhibitors	benazepril, lisinopril, quinapril, ramipril
Agents for gout	allopurinol, colchicine
Antiarrhythmics	digoxin, disopyramide, procainamide
Antibiotics	aminoglycosides, penicillins, quinolones, cephalosporins, sulfonamides, vancomycin
Antihypertensives	hydralazine, methyldopa
Antineoplastics	methotrexate
Antivirals	acyclovir, amantadine
Beta blockers	acebutolol, atenolol, nadolol, sotalol
Calcium channel blockers	verapamil
Gastrointestinal agents	cimetidine, famotidine, metoclopramide, nizatidine, ranitidine
Opioid analgesics	codeine, meperidine*, morphine
Oral hypoglycemics	chlorpropamide

* meperidine is metabolized to the renally excreted neurotoxin, normeperidine

$$Cl = [(140 - \text{age}) \times \text{weight(kg)}] \div [\text{Serum creatinine} \times 72]$$

The result should be multiplied by 0.85 for women. This formula estimates creatinine clearance in people who are at least five feet tall, are not obese, have no severe muscle wasting, and have stable renal function.

Drugs which are primarily eliminated via the kidney may accumulate in the elderly, especially in those individuals with significant renal insufficiency (Table 1). The dosage of renally eliminated drugs, including many antibiotics (cephalosporins, penicillins, aminoglycosides), cardiovascular agents (digoxin, atenolol), histamine-2-receptor antagonists (ranitidine, famotidine, nizatidine), and many

other classes of drugs, needs to be reduced in the elderly patient with renal insufficiency in order to prevent significant adverse effects due to drug accumulation. Also, many drugs have active or toxic metabolites which are renally eliminated and can accumulate with declining renal function. Examples include procainamide, meperidine, codeine, and chlorpropamide.

Renal clearance of digoxin is reduced in proportion to the reduction in creatinine clearance. Its half life is 36 hours in younger patients with normal renal function and may be twice as long in older patients with poor renal function. While the serum digoxin concentration is useful in monitoring therapy, it should be remembered that the elderly may show signs of central

nervous system toxicity such as restlessness, malaise, agitation, confusion, and visual symptoms when the serum concentration is in the high end of the therapeutic range (> 1.5 ng/mL).⁶

PHARMACODYNAMIC CHANGES

If doses are adjusted for the changes in pharmacokinetic parameters previously mentioned and a greater than expected drug effect still occurs, then enhanced pharmacodynamics may exist. Pharmacodynamics refers to the drug effect that occurs on a cellular or receptor level and is more difficult to evaluate than other age-related drug changes. For example, due to blunting of baroreceptor sensitivity, postural hypotension in the elderly is common in response to certain

TABLE 2. Criteria of Inappropriate Medication Use in the Elderly ^{10,11}

Class	Drug	Prescribing concern
• Cardiac medication	• disopyramide • methyldopa, reserpine • digoxin • dipyridamole	• negative inotrope, anticholinergic • depression, sedation • use dose <0.125 mg/d except for treatment of atrial arrhythmias • orthostatic hypotension
• sedative-hypnotics	• chlordiazepoxide, diazepam, flurazepam • barbiturates	• use short-acting drugs • highly addictive and sedating
• antidepressants	• amitriptyline, doxepin	• strong anticholinergic, overly sedating
• NSAID	• indomethacin • phenylbutazone	• CNS side effects • hematological side effects
• hypoglycemics	• chlorpropamide	• prolonged hypoglycemia
• analgesics	• propoxyphene • pentazocine • meperidine	• low efficacy • confusion, hallucinations • neurotoxicity - metabolites
• platelet inhibitors	• ticlopidine • dipyridamole	• no advantages over aspirin
• anxiolytics	• meprobamate	• highly sedating, addictive
• over-the-counter products	• combination cold products, antihistamines	• anticholinergic • use lower dose with caution
• antispasmodics	• dicyclomine, belladonna alkaloids	• highly anticholinergic, questionable efficacy
• muscle relaxants	• methocarbamol, oxybutynin, carisoprodol, cyclobenzaprine	• sedation • anticholinergic • weakness
• antiemetics	• trimethobenzamide	• relatively ineffective, may cause extrapyramidal side effects

drugs such as antihypertensive agents and antipsychotics.⁷

Some age-related changes in central neurotransmitters have been noted, even though clinical deterioration may not be apparent. Central cholinergic mechanisms as measured by the marker enzyme choline acetyltransferase are deficient in some, but not all, areas of an older person's brain.⁸ Consequently drug-induced confusion is a more frequent adverse event in the elderly. The elderly are also more sensitive to anticholinergic side effects which include blurred vision, confusion, disorientation, palpitations, worsening of glaucoma, and urinary retention.

In summary, although there are pharmacokinetic changes related to the normal aging process, most are not significant by themselves. Significant drug-drug interactions and unexpected drug effects can occur when these age-related changes are combined with comorbid conditions and the use of concomitant medications. It is important, therefore, to consider all these factors, as opposed to focusing on a single pharmacokinetic parameter that may be slightly altered.

ADVERSE DRUG EVENTS IN THE ELDERLY

The risk associated with adverse drug reactions increases with the number of medications consumed, advancing age, and the presence of multiple pathologic conditions. Brennan and colleagues reported on the prevalence of medical and surgical iatrogenesis in community hospitals in a retrospective review of more than 31,000 admissions.⁹ Trained nurse reviewers screened for adverse events which were then verified by two independent and specially trained physicians. The overall rate for iatrogenic events was 3.7% and standardized rates of adverse events increased with advancing age. Drugs accounted for about 20% of all the iatrogenic events, half of which occurred in operative settings. Approximately

It is important to understand physiologic age-related changes and their impact on pharmacokinetics and pharmacodynamics.



50% of the drug-related events were judged to be due to substandard care.⁹ While this retrospective review involved judgment or subjective decisions about clinical issues, the question remains: How can we improve prescribing of medications so that preventable drug-related events do not occur?

The appropriate use of medication in the elderly is important, and reducing inappropriate drug use may be one of the best and most cost-effective ways to improve the quality of care. In the

elderly, adverse reactions may affect cognition, mobility, emotional state, and continence. Adverse drug events may be unavoidable consequences of pharmacokinetic drug interactions or idiosyncratic effects of medications, or may be related to inappropriate prescribing.

Two different methods for evaluating prescribing have been studied in older persons. Beers and colleagues, using a consensus panel approach with experts in geriatric medicine, developed a list of drugs whose use in the elderly was viewed as contraindicated.^{10,11} These criteria represent the current state of knowledge, and current opinion, both of which may change as more data on the beneficial and toxic outcomes of medication use become available.¹² The "Beers" criteria are likely to be useful for examining the extent of inappropriate use in clinical settings. Drugs included by the consensus panel are those with little

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accepted efficacy data such as propoxyphene, drugs with undesirable pharmacokinetic profiles such as diazepam, and drugs with a high chance of side effects such as amitriptyline. Some of these medications and the rationale for their inclusion are listed in Table 2. Using this consensus criteria in nursing home residents¹⁰ and the community dwelling elderly,¹² a high rate of inappropriate prescribing was detected. This method, however, detects potential and not actual prescribing problems. No published study links the prescription of the "Beers" medications with adverse clinical outcomes in older patients.

The second method for evaluating prescribing, developed by Hanlon and colleagues, is a comprehensive medication assessment instrument which evaluates each medication of a patient's regimen in ten component areas of prescribing. These areas include linking each drug with a diagnosis, assessment of efficacy for that diagnosis, dose, dosing regimen, evaluation of drug/drug interactions, evaluation of drug/disease interactions, duplication of therapy, duration of therapy, and relative cost.¹³ These comprehensive criteria, while more complex and time consuming than the Beers' criteria, may yield recommendations for improvements in a patient's overall drug therapy regimen. They have been validated between physician and pharmacist raters and the component parts of the assessment are weighted so that a total score can be computed.

To compare these two methods of evaluating drug prescribing, the use of indomethacin 25 mg tid for 2-4 days to treat an acute attack of gout would be listed as inappropriate by the consensus criteria but not by the medication assessment instrument. The ability to link a drug with the disease, a dose, duration of therapy, and other patient characteristics makes this latter evaluation technique flexible in the clinical environment. In an outpatient

Veteran's Administration Medical Center, this technique detected and corrected inappropriate prescribing.¹⁴ Patients with higher medication assessment instrument scores are more likely to report and be treated for adverse drug events.¹⁵

An important aspect of the clinicians' role in safeguarding the elderly from adverse drug reactions is careful assessment, monitoring, and education. When the elderly are prescribed a new drug, it should be made certain that the diagnosis is suitable for the specific drug therapy, because not all illnesses which afflict the elderly require drug therapy. However, while it is wise to avoid drugs if possible, appropriate drug therapy should not be withheld if the drug would improve quality of life.

PRACTICAL GUIDELINES FOR PRESCRIBING IN THE ELDERLY

Greater knowledge of the pharmacokinetic and pharmacodynamic effects of age-related changes should lower the incidence of adverse drug effects in the elderly. The clinician should develop a medication database for each elderly patient, which includes all drugs, including prescription, over-the-counter, natural or herbal products, and "borrowed" or saved medications. Such a list can help prevent drug-induced disease and drug-drug interactions.

Today many of the elderly self-treat with natural products. Natural products may have benefits, side effects, and drug interactions. Although some clinical trials with natural or herbal products have been published, it is unknown if the product obtained from the local health food store is identical, or even similar, to the preparation in the study. (See Glen et al, in this issue.)

General rules for geriatric pharmacotherapy include: (1) start with a low dosage and increase slowly; (2) be aware that the half-life of many drugs

can be prolonged in the elderly, due to pharmacokinetic changes (such as renally eliminated medications); (3) use the fewest number of drugs as possible; (4) watch for signs of toxicity - at the start of therapy and periodically thereafter; (5) be able to identify a new illness which may actually be a drug-induced disease.

Compliance can be a problem. If the expected response is not achieved from the medication, poor compliance could be the reason. (See Geletko and Rana, this issue.)

The contribution of aging toward health status is an issue that all health care practitioners face. It is important to understand physiologic age-related changes and their impact on pharmacokinetics and pharmacodynamics. In addition, it is important to realize that concurrent medications and disease states often play a major role in these parameters, as well. The elderly are a heterogeneous group and therapy must be individualized. Integrating all these factors into drug therapy decisions can decrease the likelihood of adverse events.

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Improving Adherence with Complicated Medication Regimens

Sandra M Geletko, PharmD, and Khurram Z. Rana, PharmD

Patient medication adherence is crucial to the successful treatment of chronic disease states such as asthma, hypertension, diabetes, epilepsy, tuberculosis and HIV infection. Poor adherence can delay the goals of pharmacotherapy and lead to therapeutic failures, hospitalizations, and loss in economic productivity totaling billions of dollars annually.^{1,2} Health care practitioners must ensure that patients, who have the ultimate decision to deliver their own therapy, are taking their medications appropriately. Nonadherence can occur with patients of all ages. Patient adherence becomes even more of a challenge with multiple medications.

Several studies have shown that adherent patients survive longer and do clinically better than non-adherent patients. Following a myocardial infarction, men who took less than 75% of their medication were more likely to die than those who adhered to the medication.³ HIV-infected women who were > 80% adherent to fluconazole prophylaxis for mucocutaneous candidiasis were less likely to develop candidal infections than their counterparts who were < 80% adherent.⁴

FACTORS INFLUENCING ADHERENCE

Nonadherence should not be seen simply as patients' delinquency in disregarding professionals' instructions. Practitioners must consider the willingness of patients to take medications. Table 1 lists the obstacles to good medication adherence.⁵ To improve adherence, practitioners must understand these obstacles, which are often multifactorial.

Adherence can be influenced by patients' perceptions of their health. Patients who do not understand or ac-

cept the diagnosis, or disagree with the physician, may not adhere. Patients who make their health a low priority or who see no immediate benefits to therapy may not adhere (as with hypertension medications). If patients do not believe that therapy will be beneficial, they will be lax.

Patients who misunderstand the adverse effect profile may not adhere to a regimen. If patients believe that the risk of a side effect is too great, they may stop taking their therapy at the first onset of any side effect, no matter how minor. Practitioners must explain the importance of taking the medication and how that will impact on the course of a disease state.

Poor communication between the patient and the physician, pharmacist, or other healthcare provider contributes to poor adherence. Many patients forget important issues discussed with the practitioners; therefore, information should also be provided in written form. For HIV infection, the onslaught of new information can overwhelm the patient. The mental and emotional stress of beginning a drug regimen, to be taken indefinitely, can also prevent patients from comprehending much of the medication counseling on a first clinic visit.

Patient nonadherence may be due to complex regimens, especially those involving multiple agents. The elderly may have trouble adhering because they are taking many medications. Often simplifying the dosing regimen can improve adherence. Patients are more adherent to a regimen given once daily versus one dosed more frequently.^{6,7} However, reducing the frequency may not be an option because some medications are not available in

Abbreviations Used:

DOT	directly observed therapy
HIV	human immunodeficiency virus
NNRTIs	non-nucleoside reverse transcriptase inhibitors
VAMC	Veterans Affairs Medical Center

once- or twice-daily dosage forms. In addition, simply placing a patient on a once-daily regimen might not improve adherence if the obstacle to adherence is miscommunication or other apprehensions.

Finally, the cost of medications influences adherence. If patients cannot afford prescriptions, they will not have them filled. In addition, the financial assistance for medications available to some patients may entail paperwork or extra clinic visits - themselves a deterrent.

SOLUTION TO NONADHERENCE WITH TUBERCULOSIS TREATMENT

While not considered classic chronic diseases, infections present a unique challenge because poor adherence could allow resistant strains to emerge. Tuberculosis, for instance, requires treatment with multiple agents over prolonged periods of time to treat the infection and reduce resistance development.⁸ Resistance to one or more drugs was found in 10-15% of cases;

Table 1. Obstacles to Good Medication Adherence⁵

- Patient perceptions of disease state
- Miscommunication
- Unresolved concerns about medication use
- Regimen complexity
- Cost

Table 2. Obstacles to Good Medication Adherence in HIV-Infected Patients

- Social stigma
- Disease denial
- Substance abuse
- Care for HIV-infected children
- Homelessness
- Financial constraints
- Access to care
- Complex drug administration issues

in particular, almost 10% of cases were resistant to either isoniazid or rifampin, or both.^{9,10} While both social and behavioral factors affect drug failure and the reemergence of this disease, patient nonadherence has played a substantial role. Nonadherent patients were reported to take almost four times longer to become culture negative than those who were adherent.¹¹ Even more disconcerting, 25% of patients with active tuberculosis failed to complete treatment within 12 months.¹² This nonadherence has created a severe public health threat. One strategy to circumvent the risk of patient nonadherence is directly observed therapy (DOT). In a study of patients with active tuberculosis disease, DOT significantly reduced the acquisition of drug resistance and relapse.¹⁰ In response to the increasing number of tuberculosis cases and threat of drug-resistant strains, the CDC has recommended DOT for all patients with active tuberculosis.¹³

THERAPEUTIC MANAGEMENT OF HIV INFECTION: A CASE MODEL IN COMPLEX MEDICATION REGIMENS

Management of HIV infection is becoming similar to management of a chronic disease process, in contrast to the beginning of the HIV epidemic where patients experienced a rapid decline in health status. Today HIV can be treated in its asymptomatic state. Therapies generally include a minimum of three antiretroviral agents,¹⁴ in addition to agents used to prevent the

development of opportunistic infections in patients with CD4+ counts less than 200/mm³. Several issues need to be considered with these complex HIV-related therapies before a health care provider can optimize a patient's adherence.

Nonadherence with HIV-related medication regimens will lead to sub-optimal outcomes, some of which can have public health ramifications. Nonadherence with protease inhibitor therapy has led to rapid HIV resistance development.^{15,16} Because cross resistance can occur among the protease inhibitors, patients whose HIV develops resistance to one protease inhibitor may have limited antiretroviral therapy options in the future. Although non-nucleoside reverse transcriptase inhibitors (NNRTIs) are now available for use in combination therapy (e.g. nevirapine, delavirdine), these agents are not as effective after a patient has been on protease inhibitor therapy.¹⁴ Therefore, assuring excellent medication adherence is crucial.

Nonadherence should not be seen simply as patients' delinquency in disregarding professionals' instructions.



Where providers and patients may agree that good adherence is essential, HIV-infected individuals encounter barriers to adherence similar to individuals taking complex medication regimens chronically, in addition to some disease state-specific barriers (Table 2). Women infected with HIV often experience more obstacles than men. Health care providers must recognize the adherence deterrents that confront an HIV-infected individual. As with tuberculosis, DOT has been suggested for individuals taking protease inhibitor combinations.¹⁷ While DOT may ensure excellent adherence and decrease HIV resistance development, logistically the health care sys-

tem is not prepared to monitor thrice daily medication regimens. Furthermore, the treatment of HIV infection is a patient choice. The dual challenge to health care providers is to encourage those patients refusing medication to consider therapy, and to motivate those who acquiesce to therapy to remain adherent.

PHARMACIST-DIRECTED CLINIC

The Providence Veterans Affairs Medical Center (VAMC) initiated a Pharmacist-Directed Protease Inhibitor Clinic, designed to screen patients for commitment to protease inhibitor therapy, and then counsel and educate patients on their antiretroviral therapy. For patients who are not yet willing to commit to therapy, the Clinic provides close follow-up with education, to offer them protease inhibitors when they are ready.

The Providence VAMC HIV Clinic serves approximately 55 patients. Currently, 26 are taking protease inhibitor or NNRTI triple therapy combinations. Physicians refer patients before the initiation of therapy. The initial clinic visits include laboratory screening, a review of past refill records, and screening for potential drug interactions. The patient is told that he or she must be committed to taking the protease inhibitor combination as directed for optimal benefit. The role of the viral load and CD4+ counts with respect to HIV infection progression and in monitoring therapy are reviewed, so that all patients will understand how to interpret a response to therapy. Written information sheets on the new antiretroviral therapies are explained. A 24-hour clinical pharmacist's pager number is given to patients in case they have questions about their medications or consider stopping their therapies. Patients are phoned one week after starting a protease inhibitor combination to assess tolerance and adherence. Both the pharmacists and physicians emphasize that the patient is entering into a verbal contract to take his protease inhibitor combination as directed. Some patients are not prepared to take a complex medication regimen. For these

Table 3. Measures which can increase patient adherence

- Lessen dosing frequency
- Educate about benefits of therapy
- Educate about outcomes of poor adherence
- Employ dosing reminders (e.g., timers, pill boxes)
- Engage social support

patients, at each visit the physician will assess the patient's readiness to commit to a triple combination antiretroviral regimen. In some cases, the physician will refer the patient to the pharmacist for additional education on aggressive antiretroviral therapy, so that the patient has the information to decide on his drug therapy.

Follow-up visits to the Pharmacist Clinic have revealed several adherence problems in patients taking protease inhibitors. One of the most common dosing problems with patients prescribed thrice daily medications is the mid-day dose: patients miss it when they are not home. Second, adverse drug effects may motivate patients to stop therapy, either temporarily or indefinitely. Third, the patient may be complying with the correct number of doses per day, but taking the medication incorrectly, at the wrong time with respect to dosing interval or meals. Finally, patients are not adhering to adjunctive dosing measures, such as adequate hydration with indinavir (Crixivan®).

STRATEGIES TO IMPROVE ADHERENCE

Several measures can facilitate adherence (Table 3). If a patient is committed to antiretroviral therapy, but the dosing frequency becomes a hindrance, agents dosed twice daily rather than thrice daily may be preferred. Patients who work may have difficulty taking a medication one hour before a meal. These patients might do better with medications that can be taken with

meals (although patients who must take medication in lunchrooms with coworkers may face embarrassment). Association of dosing with daily events such as a meal or television program can enforce regular dosing. Some patients may need a pill box to carry a mid-day dose or a pill minder. Some patients may have family or caregivers who arrange their medications in pill boxes for each day of the week. Whenever family or friends participate in the patient's care, the individual has a stronger chance of adhering to therapy.

Since side effects with antiretroviral therapies are more pronounced in the first few weeks of therapy, patients need encouragement to endure the discomfort of initial side effects and continue treatment. Repeated reinforcement is essential for some patients, who need to be reminded of the potential for their HIV to mutate to a strain which our current therapies cannot fight. Laboratory or clinical data may also reinforce adherence. For HIV, viral load and CD4+ count results can be shared with patients to show them how well the medications are working. Once again, stressing to patients the need for absolute adherence to keep a viral load below the limits of detection is important. In some cases, patients have been able to discontinue therapies, such as antifungals for recurrent oral thrush, after initiating triple antiretroviral therapies. It can be emphasized that this discontinuation of a therapy happened because the patient was taking the antiretroviral therapies correctly.

The model developed at the Providence VAMC is one approach to the management of complex medication regimens. Due to the number of details that need to be included in educating patients initiating antiretroviral therapy, a separate clinic appointment with the clinical pharmacist has relieved some of the burden from physicians, who have other issues to address in their 30 minute time slot with the patient. Patients have found the education and close follow-up comforting and helpful.

APPLYING THE HIV MODEL TO OTHER DISEASE STATES

When compared to management of other disease states which may employ complex medication regimens, HIV infection may not be unique. With HIV infection, the full gamut of health status is seen. Therefore, facilitating medication adherence for a symptomatic HIV infection can be similar to motivating a hypertensive patient to adhere to medications and lifestyle changes which will prevent complications several years later, even though immediate disease state symptoms and effects of nonadherence may not be seen. Alternatively, symptomatic HIV infection can be likened to disease states with both short and long-term consequences of nonadherence, such as diabetes. Nonadherent diabetic patients may immediately notice symptoms, sometimes severe, see laboratory markers which identify nonadherence, as well as risk serious complications in the future. For these chronic disease states, the strategies of changing dosing frequency, increasing social support, and giving patients positive reinforcement should encourage adherence. A visual display of the patient's blood pressures or glycosylated hemoglobin values over time can provide feedback. Again, working with patients to help them schedule their doses in harmony with their daily routines is paramount for long term steady adherence.

PREDICTING MEDICATION ADHERENCE IN THE FUTURE

As DOT and pharmacist-directed clinics are discussed as measures to facilitate medication adherence, could resources be streamlined by predicting which patients will be nonadherent? We are studying this question regarding antiretroviral therapies and antituberculous preventive therapy, using the Transtheoretical Model of Change or Stages of Change Model.¹⁸ This model posits five stages which an individual goes through before making a sustained behavior change: precontemplation, contemplation, preparation, action and maintenance. In the precontemplation

stage, the individual is not considering a behavior change in the next six months. In the contemplation stage, the individual is considering a behavior change in the next six months. In the preparation stage, the individual is considering a behavior change in the next 30 days. In the action stage the individual has begun the behavior change; in the maintenance stage the behavior change has continued for at least six months. Several strategies and techniques (processes of change) are used by individuals in moving from one stage to another.¹⁹ For instance, consciousness raising (e.g., information and education regarding the behavior change) has helped patients move from precontemplation to contemplation. Stimulus control (e.g., a medication timer) has helped an individual move from a action to maintenance. Tailored interventions based on the patient's stage of change are preferred.²⁰ This data suggests that uniform counseling of patients may not be effective. For patients in a precontemplation stage we may want to educate about the benefits of a particular therapy; for patients in an action stage who forget some doses, timers may be the best intervention. A screening tool such as staging a patient's readiness to change will be a key instrument in developing interventions to improve adherence. This tool will be essential with complex diseases and medication regimens which carry with them barriers to proper dosing.

CONCLUSION

Excellent patient adherence can optimize therapeutic outcomes and save health care costs. Reasons for nonadherence are multifaceted; therefore, the approach to improving adherence, especially to complicated medication regimens, will also be multifaceted. A patient's readiness to adhere to a medication regimen is crucial in the process of appropriate medication-taking behavior. A promising method being studied to assess this readiness is based on the Stages of Change Model. Medication education and dose scheduling assistance are needed for patients in all stages of ad-

herence to complicated therapies to ensure proper medication use. Special clinic time devoted to assisting patients taking complicated medication regimens with dosing strategies and adherence aids can help patients to take their therapies appropriately.

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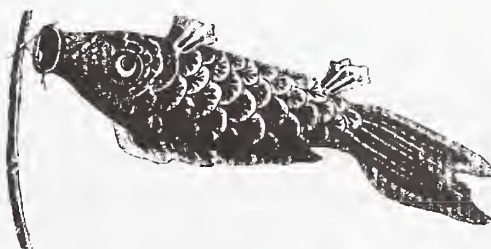
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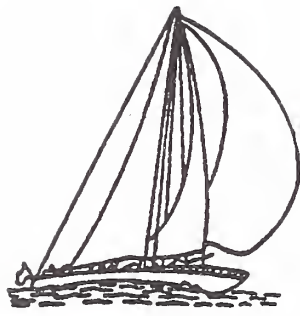
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**Rhode Island
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Edward Westrick, MD

Health Care Quality Improvement in Rhode Island

Rhode Island Quality Partners (RIQP) is pleased to introduce a regular column in *Medicine and Health/Rhode Island* on health care quality improvement. The column will primarily consist of updates on RIQP projects. However, we welcome contributions from the entire health care community in Rhode Island. The column will try to be consistent with theme issues of the journal. Since this issue focuses on medication use, I will share with you some of our projects related to quality in medication use. First, let me take this opportunity to remind everyone who RIQP is and what we do. In the process I shall touch on some of the "alphabet soup" in our increasingly complicated health care system.

ALPHABET SOUP

RIQP is the HCFA-contracted QIO in RI. HCFA is the Health Care Financing Administration, the largest purchaser of health services in the world. HCFA administers Medicare and Medicaid in US states and territories. In each state and territory, HCFA contracts with a QIO to work with providers to improve the quality of care for Medicare beneficiaries. QIO stands for Quality Improvement Organization. You may remember QIOs as PROs or Peer Review Organizations. The former PRO in Rhode Island, Medical Synergy, went by the name of Health Care Review for many years. The PROs, and PSROs (Professional Standard Review Organizations) before them, worked for HCFA to assure health care quality for Medicare beneficiaries. The activities in the early years largely focused on case review. Many of you will remember letters from the PRO notifying you of a quality issue in the care of a Medicare patient, discovered through case review.

This system of feedback created an often antagonistic relationship between the PRO and the provider community, and did little to improve the overall quality of care provided. In the early 1990s, the Institute of Medicine (IOM) made recommendations to HCFA on how to be more effective in improving the overall quality of care. This report influenced not only HCFA but the Joint Commission on the Accreditation of Healthcare Organizations

(JCAHO). Essentially, it was recognized that traditional Quality Assurance methods, that sought to identify and eliminate the "bad apple," did not improve overall quality. A new philosophy of Continuous Quality Improvement (CQI) was advocated.

HCFA's new approach, the Health Care Quality Improvement Program (HCQIP), is designed to bring the philosophies and methods of CQI to bear on improving health care for Medicare beneficiaries. It is helpful that other key drivers of health care quality endorse these same philosophies and methods. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA) have become the major watchdogs of quality for hospitals and plans, respectively. Recently, the American Medical Association (AMA) entered the mix, offering to accredit physicians. You should know some of the alphabet soup of these organizations. The JCAHO will be using a system called ORYX to measure the performance of health care organizations. ORYX is not an acronym, but a mythical creature. The NCQA uses the Health Plan Employer Data and Information Set (HEDIS) to measure the performance of health plans. The AMA is currently developing the American Medical Accreditation Program (AMAP) for measuring the performance of physicians.

RIQP PROJECTS

RIQP has a number of projects underway and is currently planning the next wave of projects. Many of these have to do with the quality of medication use. In this issue I will describe the projects and their settings. In future issues I will share numbers with you.

In the hospital setting we have three projects underway: Acute Myocardial Infarction, Community-Acquired Pneumonia, and Stroke Prevention. In the Acute MI project we are looking at a number of medication use indicators: use and timeliness of thrombolytic therapy, use and timeliness of aspirin, discharge on beta blockers, calcium channel blockers, ACE inhibitors, and aspirin. In the Pneumonia project we are primarily looking at the timeliness of the first

dose of antibiotic therapy. In Stroke Prevention we are looking at warfarin and aspirin use in atrial fibrillation.

In the ambulatory setting we have a stroke prevention project, also looking at anticoagulation for atrial fibrillation. We are developing a Congestive Heart Failure project that will look at ACE Inhibitor use. Our influenza immunization project for this year is coming to a close.

Our projects go well beyond medication use issues. Some of the projects mentioned above look into other aspects of health care quality unrelated to medication use. Other projects, not related to medication use, include mammography screening for early detection of breast cancer, dilated funduscopy examination for early detection of diabetic retinopathy, and pressure ulcer prevention and treatment in long term care.

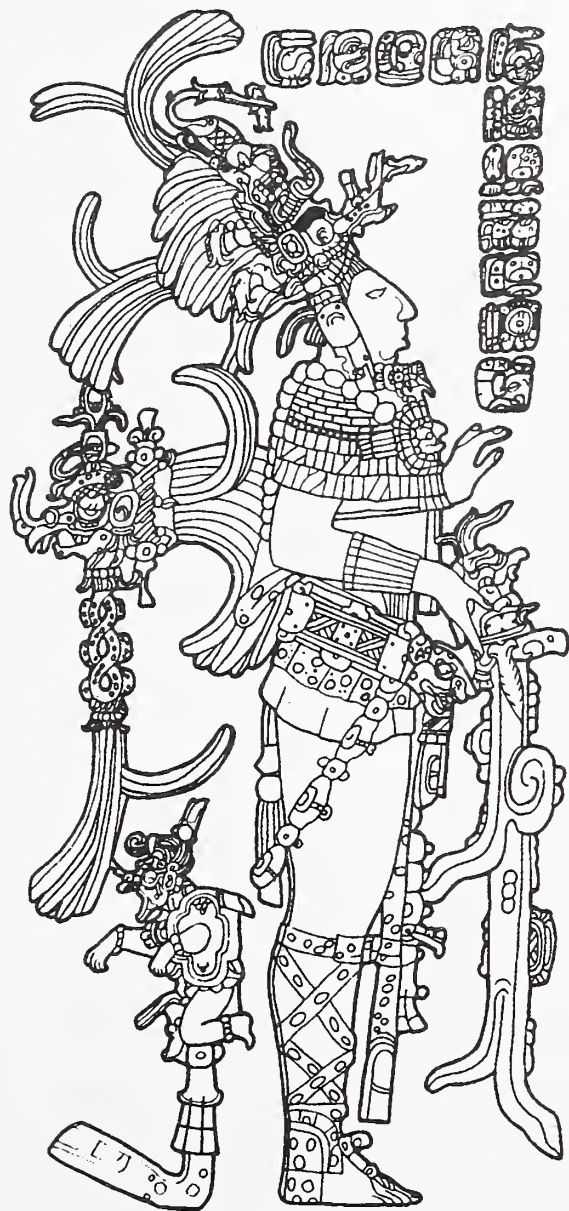
LOOKING AHEAD

Medication use will, however, continue to be an important focus of health care quality improvement efforts. We are learning more and more about medication errors and avoidable adverse events. Polypharmacy continues to be a problem and will likely increase as patients with multiple chronic diseases live longer and longer. Patient compliance with therapeutic regimens remains an ubiquitous problem. Overuse of potentially harmful medications continues in many settings.

To improve performance in these areas, we need reliable and valid instruments for measurement. These measurements should be unobtrusive to the providers and should satisfy the concerns of the quality watchers. A national effort is underway to create such a measurement system for medication use quality. The goal of this effort is to produce a handbook of medication use quality indicators that will be used by all providers and watchers. This should standardize expectations for performance, measurement, and intervention. The scope of work that goes into this effort will be extensive and exciting. The details of the effort are still being worked out. However, RIQP will likely play a leadership role in this effort and there will be room for collaboration amongst providers and those with academic interest.

Please feel free to contact me about any of RIQP's projects. I can be reached at RIQP by phone (401) 528-3250, fax (401) 528-3210, or email ripro.ewestric@sdps.org.

Edward Westrick, MD, MS, is the Principal Clinical Coordinator of Rhode Island Quality Partners. He is a member of the clinical faculty of Brown University School of Medicine and the Active Medical Staff of Roger Williams Medical Center. He is currently a PhD candidate at the University of Rhode Island studying Pharmacoepidemiology and Pharmacoeconomics.




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Medicine  Health
RHODE ISLAND

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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Adverse Drug Reactions in Hospital Patients

Jay S. Buechner, PhD

Certain drugs and biological substances, or combinations, may cause toxic reactions in persons using them. If a reaction occurs when the substance was properly prescribed and properly administered, it is commonly called an "adverse drug reaction" (ADR). Excluded from this definition are instances of accidental overdose of a drug, of the wrong drug given or taken in error, of accidents in the technique or administration of a drug, and of administration of a drug with intent to harm, e.g., with suicidal or homicidal intent.

Adverse drug reactions with serious consequences (e.g., death, disability, hospitalization) must be reported to the federal Food and Drug Administration (FDA) by physicians and other health care providers.¹ The purpose of the FDA reporting system is to identify ADRs that were not discovered during the pre-marketing testing required for all new drugs. ADRs occurring among hospital inpatients in Rhode Island can be identified through the Department of Health's statewide hospital discharge database. ADRs identified through this data system are the subject of this analysis.

METHODS

Under regulations governing the licensure of hospitals, all acute-care general hospitals in the state report to the Department of Health a defined set of data items on each inpatient discharged from those hospitals. The items include detailed diagnostic information coded in the *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM).² For cases where an ADR occurred during the inpatient stay or (rarely) was the reason for admission, the diagnostic information includes

both a code describing the effect of the substance, such as tachycardia, delirium, gastrointestinal hemorrhaging, vomiting, etc., and a supplementary code identifying the presence of an ADR and describing the causative substance. Also among the reported data are patient age at admission, pa-

Table 1. Agents Causing Adverse Reactions in Hospital Inpatients, Rhode Island, October 1, 1993 - September 30, 1996.

	Number of Cases	Percent
Antibiotics	899	9.7
Other anti-infectives	294	3.2
Hormones and synthetic substitutes	1,198	12.9
Systemic agents	1,265	13.6
Agents affecting blood constituents	548	5.9
Analgesics, antipyretics, and antirheumatics	1,159	12.5
Anticonvulsants and anti-Parkinsonism drugs	433	4.7
Sedatives and hypnotics	103	1.1
Other central nervous system depressants and anesthetics	132	1.4
Psychotropic agents	574	6.2
Central nervous system stimulants	6	0.1
Drugs affecting the autonomic nervous system	112	1.2
Agents affecting the cardiovascular system	1,228	13.2
Agents affecting gastrointestinal system	69	0.7
Water, mineral, and uric acid metabolism drugs	378	4.1
Agents acting on the smooth and skeletal muscles and respiratory system	151	1.6
Agents affecting skin and mucous membrane, ophthalmological, otorhinolaryngological, and dental drugs	53	0.6
Other and unspecified drugs and medicinal substances	681	7.3
Bacterial vaccines	4	0.0*
Other vaccines and biological substances	9	0.1
TOTAL	9,296	100.0

*less than 0.05%

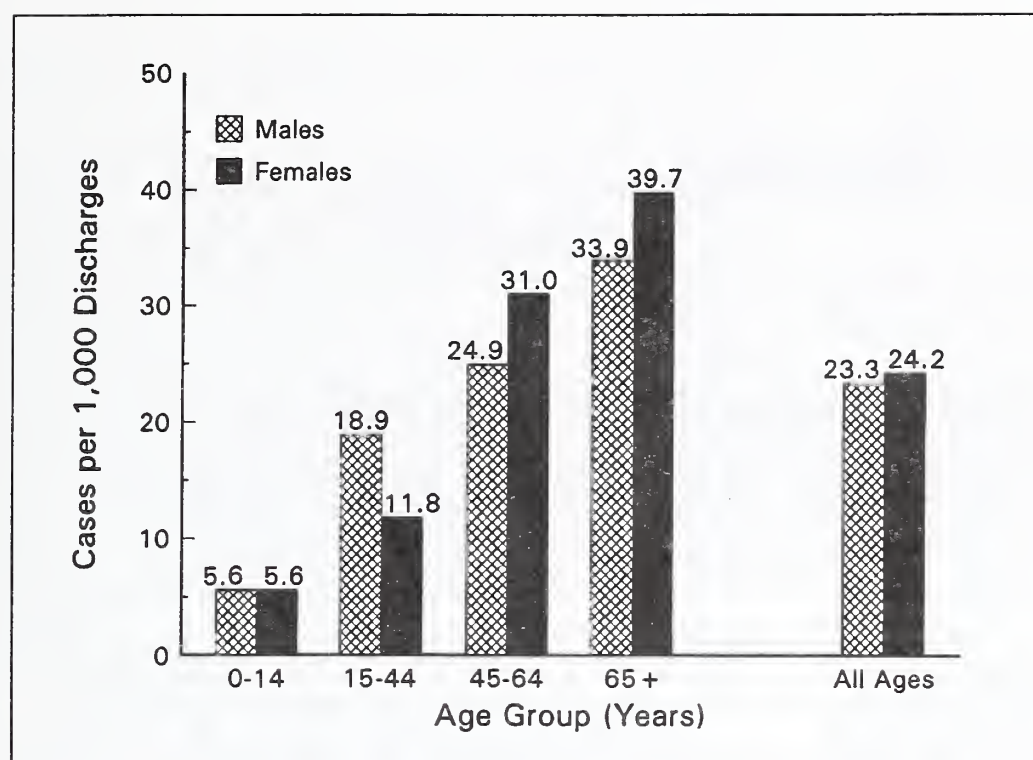


Figure 1. Discharges with Adverse Drug Reactions per 1,000 Discharges, by Age and Sex of Patient, Rhode Island Hospitals, October 1, 1993 - September 30, 1996.

tient sex, and date of discharge. These data have been analyzed to describe inpatient ADR cases during the three-year period from October 1, 1993, through September 30, 1996 (hospital fiscal years 1994 through 1996), with specific focus on the most recent three years of data.

RESULTS

Over the three years examined, 9,296 inpatients were identified with ADRs among a total of 390,489 discharges, for a rate of 23.8 cases per 1,000 discharges. The rate of discharges with ADRs increased consistently, from 23.3 per 1,000 discharges during the first year to 23.7 per 1,000 discharges the final year, for an increase of 5%. Over the three years, the number of cases of ADRs remained virtually constant while total discharges fell by 5%.

During the three years, rates of ADRs varied according to the age and sex of the patient. For all discharges, the ADR case rate during this period was 23.8 cases per 1,000 discharges. By age group and sex, the rate was lowest among males and females ages 0 to 14 (including newborns, for whom the rate was less than 0.2 per 1,000); the highest rate was among females ages 65 and older. (Figure 1) Within each sex, the rate of ADRs increased with increasing age. The largest difference in the rates for males and females appears in the age group 15 to 44 years, when the majority of hospitalizations for women are for childbirth.

Inpatient ADRs were caused by a wide variety of types of drugs or medicinal or biological substances. (Table 1) The most commonly cited drugs, based on ICD-9-CM code groupings, were systemic agents, agents affecting the cardiovascular system, hormones and synthetic agents, and analgesics, antipyretics, and antirheumatics. Among the systemic agents causing ADRs, the largest majority (1211, or 96%) were anti-neoplastic or immunosuppressive drugs.

Least commonly cited substances were bacterial vaccines, central nervous system stimulants, and other vaccines and biological substances. (These statistics do not adjust for the underlying rates of use for these substances, which are not available from this data source.)

DISCUSSION

An increasing variety of pharmaceuticals is available to physicians. Even when correctly prescribed and properly administered, however, these substances may cause adverse effects in some patients. Among hospital inpatients in Rhode Island, approximately 3,000 patients per year, or between 2% and 3% of all patients, are reported as experiencing adverse drug reactions that are severe enough to be recorded on the discharge abstract, and additional instances of ADRs occur among patients

treated in ambulatory care settings. The data presented here identify the extent to which ADRs occur among patients using prescribed medicines and support the need for physicians to report severe reactions to the FDA to support national monitoring and investigative responsibilities.¹

REFERENCES

1. See, for example: "MedWatch: the FDA medical products reporting program. How to report adverse reactions and medical product problems to the FDA." Internet: www.fda.gov/medwatch/how.htm.
2. Public Health Service and Health Care Financing Administration. *International Classification of Diseases, 9th Revision, Clinical Modification, 6th ed.* Washington: Public Health Service, 1996.

Jay S. Buechner, PhD, is Chief, Office of Health Statistics, Rhode Island Department of Health, and Assistant Professor of Community Health, Brown University School of Medicine.





Legislative Support for Access to State-of-the-Art Cancer Treatment in Rhode Island

Arvin S. Glicksman, MD, John P. Fulton, PhD, and Paul Calabresi, MD

Background

Historically, cancer mortality has been higher in Rhode Island than in the nation as a whole. In the 1970's, Rhode Island had the highest cancer mortality rate for white males among all the states, and the fourth highest for white females. Although this differential has lessened considerably over time, cancer mortality in Rhode Island still exceeds the national rate. Increased access to state-of-the-art treatment is generally believed to be one remedy. Accordingly, the Rhode Island Cancer Control Plan, published in 1989, recommended: "Promote participation in clinical trials by encouraging physicians to enroll eligible patients in phase three clinical trials, and by informing the public at large about current clinical trials, promoting the idea that all cancer patients should seek information about this form of care." Unfortunately, enrollment in clinical trials has been financially inaccessible to many Rhode Islanders, despite health insurance, because most health insurance policies did not cover the costs of investigational treatments.

Step 1: A Task Force to Increase Access to State-of-the-Art Cancer Treatment

In 1992, Senator John O'Leary sponsored legislation requesting the Department of Health to establish a Task Force to investigate problems of access to state-of-the-art cancer treatment in the State of Rhode Island. The Director of Health appointed 14 citizens, health care providers, and representatives of major health insurers to this Task Force.

The Task Force quickly concluded that the definition of state-of-the-art cancer care may not always be simple, since it must encompass multiple and dissimilar elements. Nonetheless, it identified two problems cancer patients have in gaining access to treatment: that usual physician practices may limit access to components of state-of-the-art care, and that usual reimbursement practices may deny payment for investigational treatment, including clinical trials. The Task Force recommended:

- A Cancer Patient's Bill of Rights should be written to inform the public about state-of-the-art cancer care and the importance of their advocacy in obtaining it.

- Measures to improve the planning, provision, and coordination of state-of-the-art cancer care throughout Rhode Island should be developed.
- The Rhode Island General Assembly should consider passage of legislation to mandate health insurance coverage for investigative cancer therapies when specified stringent standards are met.

Representatives of the major health insurers on the Task Force issued a minority report opposing legislated mandates for coverage, contending that they raise the overall cost of health insurance.

Step 2: Health Insurance Coverage for Off-Label Use of Drugs (94- H- 8144)

In 1993, while the Task Force was deliberating, and before it had issued its final report to the General Assembly, a bill was introduced independently which would require health insurers to provide coverage for certain prescription drugs used for the treatment of cancer, even when the drugs were not approved by the FDA for that use, i.e., "off-label use." The bill did not survive committee review. It was reintroduced in 1994 by Representative Benoit with strong support from oncologists, cancer survivors, and the Rhode Island Division of the American Cancer Society. The bill followed legislative guidelines approved in twelve other states. It was passed by both Houses of the General Assembly and signed into law by the Governor.

Under Representative Benoit's bill: insurers must cover the cost of prescription drugs even when prescribed for off-label use; insurers may dispute such use; and to settle such disputes the Director of Health may appoint an Advisory Panel of seven medical experts to determine if the disputed off-label use is medically appropriate. (The members of the Advisory Panel would include a physician appointed by a hospital and medical services corporation, a physician appointed by the Rhode Island Medical Society, three medical oncologists appointed by the State of Rhode Island Clinical Oncologists, a physician appointed by the Rhode Island Association of Health Maintenance Organizations, and a Rhode Island physician appointed by the Health Insurance Association of America.) Since enactment of this bill three years ago, no such dispute has been brought to the Director of Health.

Step 3: Health Insurance Coverage for Phase III, IV Clinical Trials (94- S- 2623 Sub B)

In 1994, based on Task Force recommendations, Senators O'Leary and Tavares introduced a bill mandating insurance coverage for investigational cancer treatments when provided as part of phase II, III, or IV clinical trials. The bill had strong support from oncologists and the Rhode Island Division of the American Cancer Society, and strong opposition from health insurers and the Small Business Association. A compromise was reached in which investigational treatments provided as part of phase II clinical trials were excluded from the mandate, and a "sunset clause" was added to terminate all provisions of the bill after two years, unless the clause was repealed before that time. The revised bill was passed by both Houses of the General Assembly and signed into law by the Governor. It took effect July 1, 1995, and became the first such legislation in the United States.

The bill requires that coverage be extended to investigative cancer therapies when they are provided under Phase III or IV clinical trials, with the following conditions:

- The clinical trials must be approved by the National Institutes of Health in cooperation with the National Cancer Institute, community Clinical Oncology programs, or the Food and Drug Administration in the form of an investigational new drug exemption, or the Department of Veteran Affairs, or a qualified non-governmental research entity as identified in the guidelines for National Cancer Institute Cancer Center Support Grants.
- Research protocols must be approved by a qualified Institutional Review Board.
- The facility and personnel providing treatment under research protocols must be qualified to do so by virtue of experience, training, and volume of patients.
- The patients receiving treatment under research protocols must meet all protocol requirements.
- There must be no clearly superior non- investigational alternatives to protocol treatments, and available clinical

cal and pre- clinical data must provide a reasonable expectation that the protocol treatment will be at least as efficacious as the non- investigational alternatives.

In January 1996 the sunset clause was repealed after a hearing of the Legislative Commission on Cancer Information Networking in which health insurers testified that the law had not raised insurance costs demonstrably.

Step 4: Health Insurance Coverage for Phase II Clinical Trials (97- S- 0001)

In January 1997 Senator O'Leary and Representative Ginaitt introduced new legislation to extend the law on insurance coverage for investigational cancer treatments to include phase II clinical trials. It is generally recognized among cancer researchers that phase II is the level of clinical investigation where advances in therapy actually occur. These advances may be tested against standard care in phase III trials, or the results of phase II trials may go directly into standard care without a randomized phase III trial. In a survey conducted in the fall of 1996, 88% of Rhode Island's oncologists indicated that they considered insurance coverage for phase II trials very important. The Brown University Clinical Oncology Group strongly supported the O'Leary- Ginaitt bill. Senior medical, surgical, and radiation oncologists all testified before the Senate and House Committees. The Rhode Island Division of the American Cancer Society wrote in support of the bill, as did many others, including many cancer survivors. Even though health insurers had not observed increased costs for the coverage of phase III and phase IV clinical trials, they strongly opposed extension of the mandate to cover phase II clinical trials. Representatives of the Small Business Association also vigorously opposed the O'Leary- Ginaitt bill. Despite stiff opposition, the bill passed the House unanimously and with only one dissenting vote in the Senate. The law contains a sunset clause which terminates mandated coverage for phase II clinical trials in December 1998, unless the clause is repealed before that time. The Governor signed the legislation into law in July 1997.

Table 1. Clinical trials availability in Rhode Island and elsewhere

Population	Trials Available	Local Contact	Telephone	Website
Adult Hem/Onc	CALGB	Dr. Louis Leone	401-444-5391	www-calgb.uchicago.edu
	ECOG	Dr. Frank Cummings	401-456-2581	ecog.dfci.harvard.edu
	BRUOG	Ms. Teresa Kennedy	401-863-9139	
Adult Surg/Onc	BRUOG	Dr. Harold Wanebo	401-456-2464	
GYN	GOG	Dr. Cornelius Granai	401-274-1100	
Pediatrics	POG	Dr. Edwin Forman	401-444-5171	www.pop.ufl.edu
NCI Trials	[Various]			ctep.info.nih.gov
Other Trials	[Various]			cancernet.nci.nih.gov

Conclusions

Rhode Island has developed a health insurance environment strongly supportive of clinical trials, making state-of-the-art cancer therapy more accessible. Physicians may offer their patients investigational treatments within clinical trials without imposing excessive financial burdens upon them or their families.

Acknowledgements

Strong community support was essential to accomplishing these legislative initiatives. The oncology community spoke at innumerable Senate and House Committee meetings, communicated with their individual representatives and senators, and encouraged their patients to do likewise. Drs. Michael Vezeridis, Sundaresan Sambandam, Louis Leone, Vishram Rege, Kirby Bland, and Harry Wanebo, as well as other members of BRUOG individually and collectively, were influential in this important endeavor. Laura Hilderly, as President of the Rhode Island Division of the American Cancer

Society, and individually as a leader of oncology nurses in the State, made many visits to the General Assembly. Marlene McCarthy frequently recruited cancer survivors to testify on the importance of these measures to their own health, and Jerry Maldavir, Director of Public Education of the Rhode Island Division of the American Cancer Society, was especially influential in many aspects of the legislative process. The undivided support of the Department of Health was particularly important for these legislative measures. Finally, without the perseverance and dedication of Mr. Paul Lupoli, who turned a personal tragedy into a force for the good of the community, these initiatives may not have come to fruition.

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John P. Fulton, PhD, is Acting Associate Director, Division of Disease Prevention and Control, Rhode Island Department of Health, and Clinical Associate Professor of Community Health, Brown University, Providence, RI.

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Book Review

The Cellular Cloud

FREDERICK W. BARNES, MD, PhD, SCHOOL OF MEDICINE, BROWN UNIVERSITY. PRINTED BY THE DEPARTMENT OF GRAPHICS, BROWN UNIVERSITY AND BY E.A. JOHNSON

In *The Cellular Cloud*, Dr. Frederick Barnes sets forth his concept of cellular defense against noxious agents. This provides an excellent framework for thinking and devising experiments to further our knowledge of biological defense mechanisms.

He begins by explaining the essence of this concept with regard to primordial single cell organisms. He postulates that when noxious substances inactivated or destroyed one of the molecules in a cell, the cell responded by making more of those molecules as compensation. In the ensuing millennia the defense process evolved to one that could make counteracting substances which could neutralize the noxious chemicals and even inactivate invading viruses. Eventually they developed the capacity to extrude these counteractive substances so as to surround themselves with a protective wall and ultimately even make some protective material that could diffuse away to act as a protective cloud at a distance from the cell. With this established, he then develops his concept of protective agents from general, non-specific, counter-active substances to one in which the protective substance evolves over time to become more specific and finally achieves the status of a specific immune response mounted by complex multicellular organisms acting in cooperation, as we know it today. Ultimately, he considers

an added modification of this process, restricting it so as to prevent a response to a fetus during pregnancy.

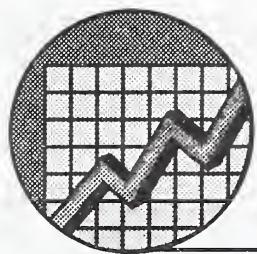


The value of this book lies in its framework for thinking of new experiments to advance knowledge in this field of resistance and immunity. Using his background as a physician and doctor of biochemistry, Dr. Barnes presents a number of his own experiments to show how one may apply his concepts to advance knowledge through research. These examples, coupled with the delightfully clear presentation, stimulate the reader to think creatively and devise new ways to further our knowledge of this field, a field which is such an essential aspect of our well-being and survival.

Reading *The Cellular Cloud* has been a pleasure. Its concepts stay with one and prompt further thought leading to new and better ways to approach expanding our knowledge in the field of resistance and immunity, thus providing many added pleasant hours of thought. Those who enjoy creative thinking in the medical research fields will find this a thought-provoking book to read and a long-lasting source of intellectual pleasure.

The value of a major contribution in science lies not only in the facts presented, but in the development of new thought and scientific paths opened for others to follow. This book succeeds admirably in this endeavor and will foster better experiments in the field of natural and acquired resistance.

— Philip McMaster, MD
Providence, Rhode Island



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	August 1997	12 Months Ending with August 1997	
	Number	Number	Rates
Live Births	1,080	13,305	13.4*
Deaths	708	10,021	10.1*
Infant Deaths	(7)	(91)	6.8#
Neonatal deaths	(6)	(74)	5.6#
Marriages	1,029	8,326	8.4*
Divorces	246	3,131	3.2*
Induced Terminations	454	5,549	417.1#
Spontaneous Fetal Deaths	62	996	74.9#
Under 20 weeks gestation	(58)	(917)	68.9#
20+ weeks gestation	(4)	(79)	5.9#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	February 1997	12 Months Ending with February 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	289	3,407	344.1	4,428.0
Malignant Neoplasms	188	2,523	254.8	6,902.5
Cerebrovascular Diseases	60	626	63.2	991.5
Injuries (Accident/Suicide/Homicide)	23	352	35.5	6,115.5**
COPD	38	444	44.8	237.5

** Excludes 1 death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

Philately in Medicine

John Tierney

∞ A Handsome Medical Fee ∞



In 1767, Dr. Thomas Dimsdale (1712-1800), an English physician, published a book on variolation. As a result, in 1768 the Russian Empress Katarina (1729-1796) [Russia, 1916, #111] invited him to perform variolation on her son Prince Pavel [Turkey, 1967, #1734].

Although many members of the court opposed the procedure, the Empress prevailed; and Dr. Dimsdale provided variolation, using Sutton's technique, employing a lancet instead of a knife, which minimized the side effects.

Dr. Dimsdale remained in Russia for several months in order to train Russian physicians in the method. Because of the favorable outcome experienced by the Prince, Dr. Dimsdale was honored and given the rank of nobility by the Empress.

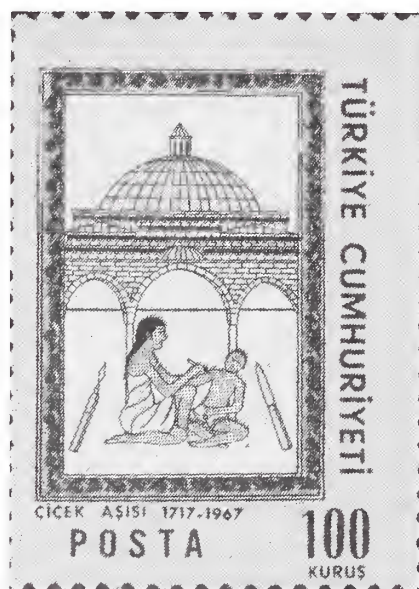
According to Dr. Joseph H. Kler,¹ Dr. Dimsdale received a lump sum remuneration of \$50,000, and \$2,500 a year until his death. He

also received from the Prince a ruby valued at \$25,000. Dr. Kler claimed that Dr. Dimsdale received the highest remuneration for a medical service in the history of medicine.

1. Kler JH. Medicine on Stamps, 1970. In: *Medical History Through Postage Stamps*. Akira Furuakawa, MD, Iskiyaku EuroAmerica Inc., St. Louis and Tokyo.

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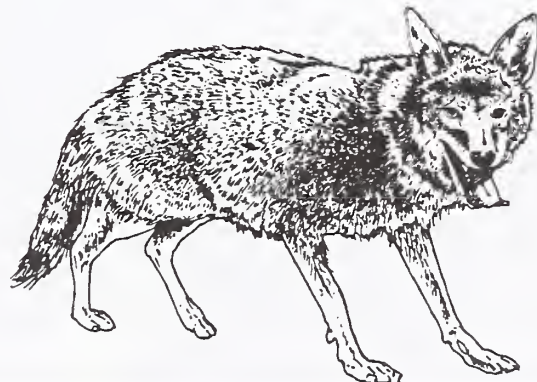
NINETY YEARS AGO

[FEBRUARY, 1908]

A.A. Barrows, MD, a Providence physician, discusses rabies in the Providence region during the preceeding year and, in particular, the two cases which he observed at Rhode Island Hospital. He provides some general epidemiologic data including the 143 deaths from rabies registered in thirty states during 1906 [which was less than the mortality figures for Russia and western Europe during the same interval.] Dr. Chapin's statistics for the Providence region indicate only six rabies deaths locally during the preceding 51 years of death registration. In the author's experience, the likelihood of developing rabies after being bitten by a rabid dog is about 15% - although facial bites run a 90% risk of culminating in clinical rabies. During 1906, 51 persons were bitten by rabid animals [either dogs or cats]. One victim, an adult woman, developed the full range of rabid symptoms despite receiving the Pasteur therapy; she died 49 days after being bitten and seven days after the onset of symptoms. A second patient, an adult male, was severely bitten by a rabid dog. He received no antirabies vaccination and died over 90 days after the bites were incurred. The author notes that 67 dogs from the streets of Providence were examined for rabies during 1906; and 26 were verified, by tissue examination, to be rabid.

This issue carries an extended obituary of a much beloved local practitioner, Dr. Clarence T. Gardner, who was born in Seekonk in 1844. He attended public schools in Pawtucket and matriculated at Brown. During the Civil War, Gardner volunteered for the Third Rhode Island Artillery and participated with distinction in numerous critical battles from Bull Run to the final drives through Petersburg to the Appomatox Court House. When mustered out, he attended Harvard Medical School and upon graduation established his practice in Providence eventually specializing in surgery and obstetrics. He died at age 62, still practicing to within days of his passing.

The United States Treasury Department advertises positions with the Bureau of Public Health, available for qualified physicians. Salaries range from \$1,600 to \$2,500 per annum. Travel and living expenses are also provided.



NOTICE TO SOUTH PROVIDENCE-BASED MEDICAL PRACTICES

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For more information, contact Mr. Kevin Woods at 831-5070,x28.

FIFTY YEARS AGO

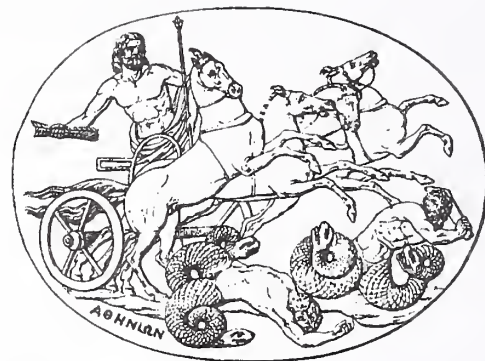
❧ [FEBRUARY, 1948] ❧

Robert V. Lewis, MD, reviews the documented cases of pneumococcic lobar pneumonia at Rhode Island Hospital for 1945 to 1947. This comprehensive analysis includes 154 adults [with 18 deaths] and 43 children [with one death.] The author concludes that the disease is more common in males [a ratio of 7 to 3]; further, that the morbidity increases in older age groups and is seasonally oriented, the highest incidence in winter and early spring. There was a preponderance of types 1 - 3 in this series. Lewis also notes the therapeutic value of antibiotics in reducing mortality and diminishing hospital stay. Penicillin in daily dosage exceeding 300,000 units is recommended.

Frederic Burns, MD, discusses cholesterol tolerance and notes that since cholesterol appears to be related to vascular changes, it might be of value to estimate the patient's tolerance to cholesterol early in life, and if such tolerance is lacking, to prescribe a cholesterol-poor diet. He believes that cholesterol atheromata, once established, cannot be decreased in size by a cholesterol-poor diet.

Two cases of Wilm's tumor, in the same family, are reported by Mihran Chapien, MD.

The Presidential Address, "The Pattern Was Established," was given by Guy W. Wells, MD, before the Providence Medical Association during its one-hundredth year of existence. The lead editorial also celebrates this centenary, noting that the Association was founded during the Mexican War, when the city population numbered 40,000 and the most pressing medical problems were cholera and smallpox.



TWENTY FIVE YEARS AGO

❧ [FEBRUARY, 1973] ❧

A short history of the development of cardiac catheterization as a major diagnostic procedure is provided by Stephen M. Jones. Through the experiments of Forssmann, Klein, Cournand and Richards, a sophisticated measurement technic has now been developed. Its avowed purpose, initially, was to measure temperatures - but now with the use of the Fick equations, such parameters as oxygen concentration may now be readily determined. The author predicts that computers will provide immeasurable aid in developing this intervention still further.

The roles of medical consultants in child psychiatry are defined and illustrated in a report by a group of Rhode Island child psychiatrists.

John R. Stuart, MD, describes the short bowel syndrome and summarizes its characteristic findings which may result from extensive surgical removal of bowel, from exclusion procedures or from enteropathy.

Thomas W. Pearlman, a local attorney, summarizes the significance of strict products liability doctrine for the physician.



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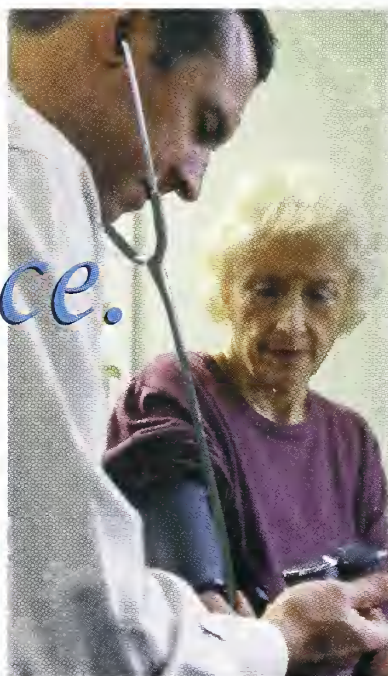
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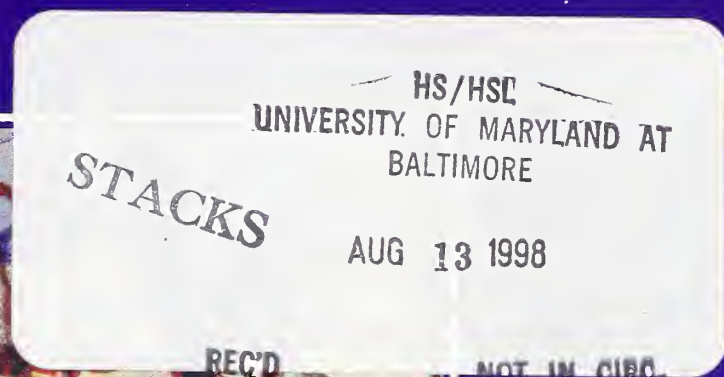
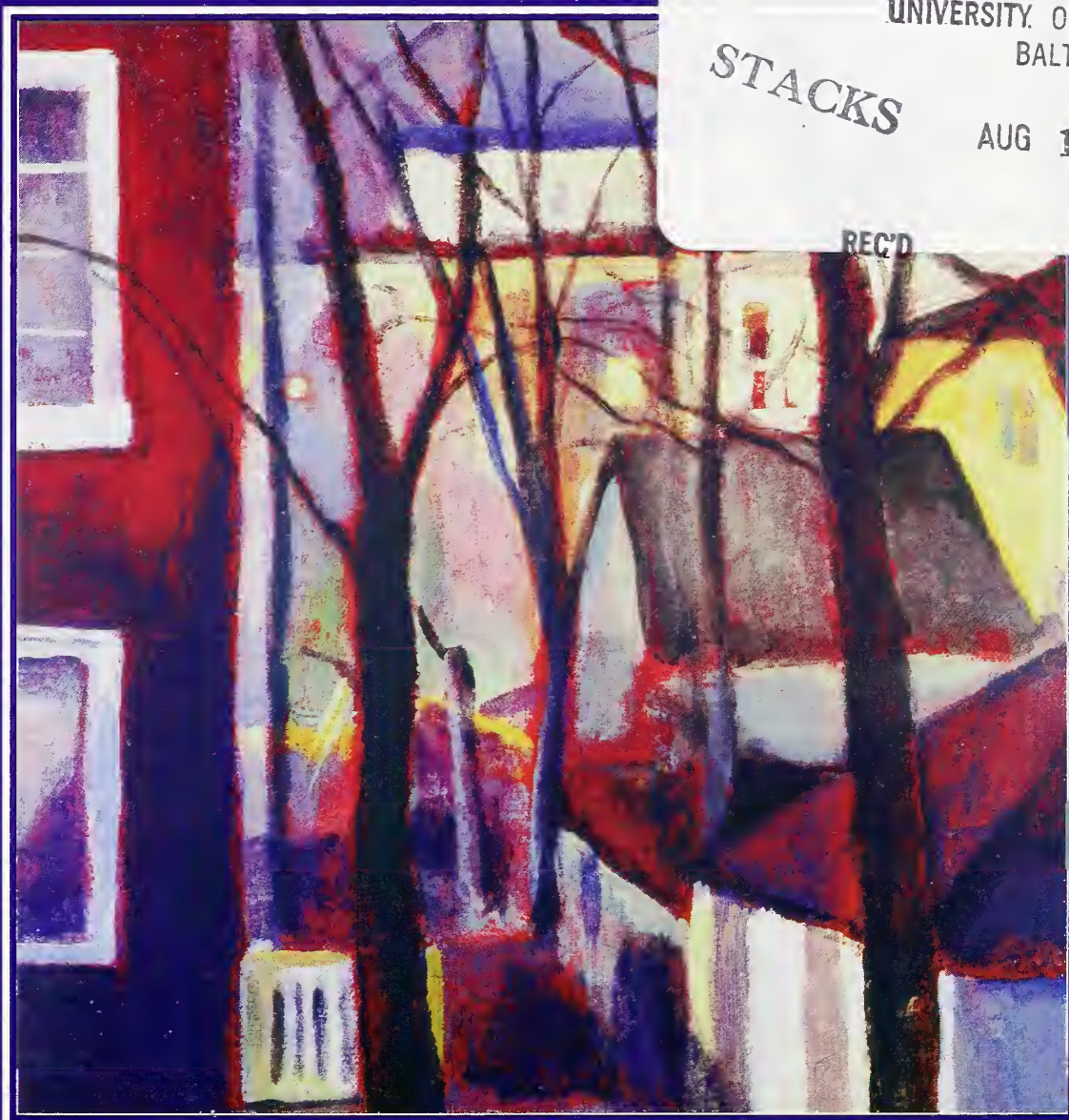
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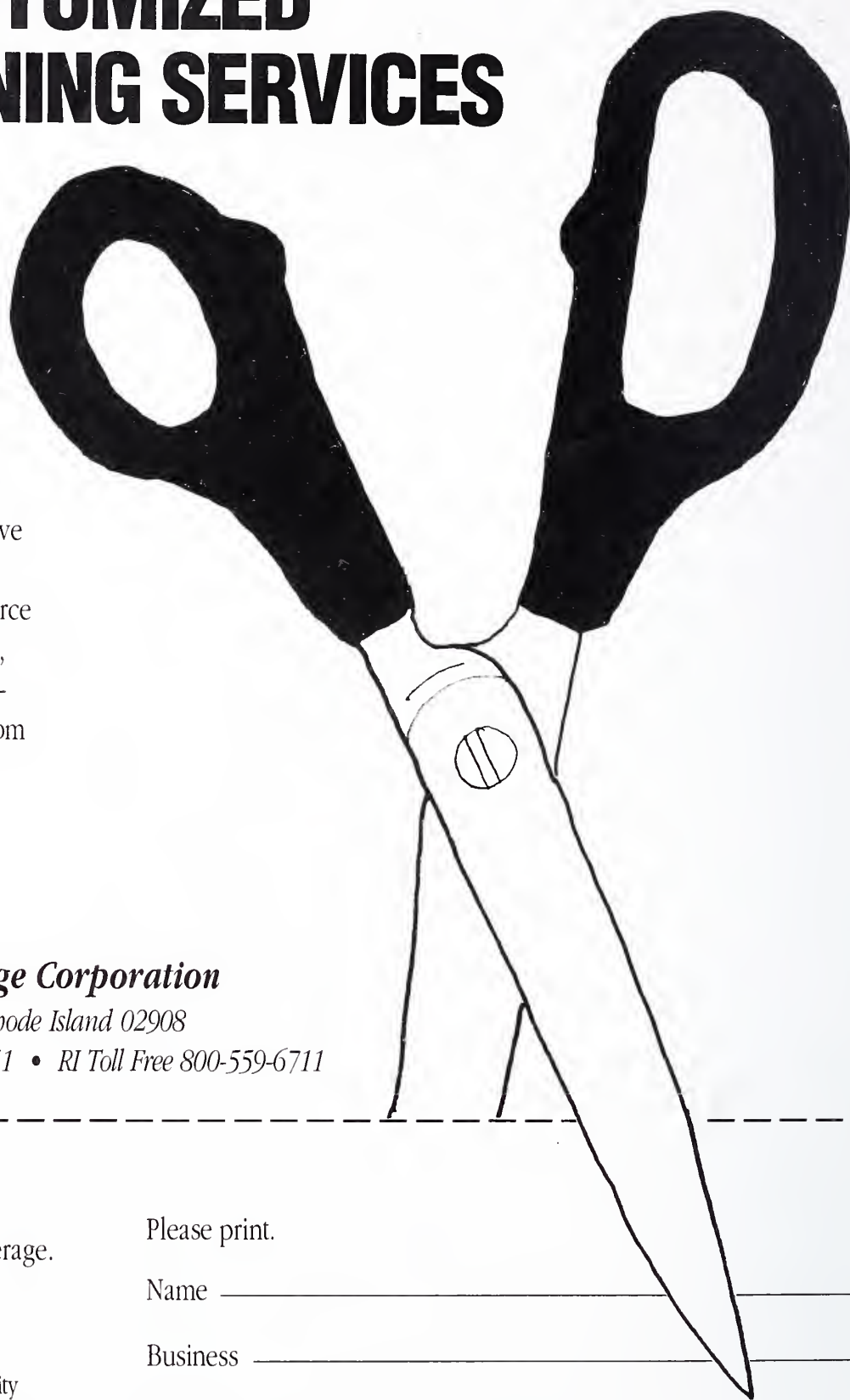
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COMMENTARIES

Opportunities and Dangers in the Changing Health Care System

Opportunity and danger are two sides of the same coin. The emergence of managed care in the United States has been hailed by some as the mechanism for restructuring our fragmented, specialist-dominated, fee-for-service medical system. Indeed, over the past half decade, the number of new specialists in some overcrowded fields has dramatically declined, as has the income of physicians in certain specialties. However, many fear that the concentration of power over consumers' choices and providers' actions in the hands of managed care companies, many of which are publicly traded, represents a real threat to the quality of medical care in the United States.

Nowhere are the concerns about the dangers more evident than when applied to vulnerable populations. Rapid enrollment growth in Medicare managed care plans has meant new opportunities for coverage at a relatively lower cost but with some restrictions in choice. This restriction of choice is not binding since Medicare beneficiaries can opt out of a managed care plan at virtually any time. However, repurchasing supplemental insur-

ance coverage policies to complement regular Medicare may be difficult and costly.

Like all other purchasers of health care, states have boarded the managed care bandwagon since it promises a relatively fixed budget obligation for a defined population of recipients. The recent Balanced Budget Act eliminated the requirement that managed care companies have no more than 25% of their subscribers under Medicaid. Florida's experience with Medicaid-only managed care companies was quite negative while other provider groups acting as a managed care company such as the Neighborhood Health Centers here in Rhode Island have been viewed more positively. Nonetheless, since states now can mandate managed care and limit the choices of companies available to Medicaid recipients, the competitiveness of local markets may be greatly undermined.

The papers in this issue exemplify both the opportunities and the dangers of managed care. Drs. Vivier and Alario describe the potential for using the national model program, RiteCare, as a vehicle to institute active outreach for immunization in a population that has historically been underserved in spite of Medicaid and public health clinics. Tricia Leddy gives a summary of RiteCare. Ms. Ehrich and her colleagues report the willingness of one managed care company to institute active outreach efforts to identify women due for mammograms. These papers speak to the advantage that managed care companies have in serving the population precisely because they are responsible



for all their health care needs.

Dr. Preston outlines the special complications facing managed care companies as they attempt to develop specialty services for the frail elderly. For those trained in geriatrics, many of the provisions made in training primary care physicians to work with frail older patients may appear obvious, but moving a whole system by introducing a new approach to care can be cumbersome. However, under a fee-for-service system there might be no push to alter the approach to caring for these patients, leaving patients to "shop" for a geriatrician (always in short supply) or another physician willing to cater to special needs. Dr. Allen reported about the experiences of persons with disabilities in Springfield, Massachusetts: their Medicaid coverage was converted to managed care, but the system of providers had not been adequately prepared. Some people with chronic illnesses organized their complex network of medical care providers in a way that worked for them. Under managed care, this ostensibly inefficient specialist-driven approach is changed, making the primary care physician the "captain" of the team. While this may be fine for the majority of the population, it may not be the most beneficial approach for patients with highly specialized medical and social care needs.

Dr. Mor's paper on the nursing home sector reveals the extent to which the introduction of managed care has affected a large class of providers. Dr. Allen's paper similarly points to the interorganizational consequences of the



introduction of managed care for community based health care agencies that work at the periphery of the medical care system. By drawing many of these "safety net" long term care providers into the highly competitive health care markets that have emerged, their ability and willingness to cross-subsidize these services without explicit state support will be increasingly limited, leaving a world of "winners and losers".

We hope that these papers stimulate readers to consider the opportunities and dangers that managed care represents for the delivery of health care to the Rhode Island population, rich and poor, old and young, healthy and chronically ill.

— Vincent Mor, PhD
— Susan M. Allen, PhD

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Speculations on the Etiology of Malaria

Malaria, a disease of both animals and man, has oppressed most populations since antiquity. And while it has been known by many different names [swamp fever, aestivoautumnal fever, ague, Roman fever, paludic fever, telluric fever] its clinical presentation is so singular - wracking chills followed by intense fever in cycles of two days [tertian fever] or three days [quartan fever] - that the disease can be readily identified whether in Sumerian tablets, Homeric poetry or the ancient Chinese texts of Nei Ching. Indeed, malaria was so common in Roman Italy that a special goddess [*Dea Febris*] had been assigned to heed the pleas of its victims.

A disease that afflicts as many a billion people will inevitably insist that two questions be answered: First, what causes it? And second, how is it transmitted from its source to its victim?

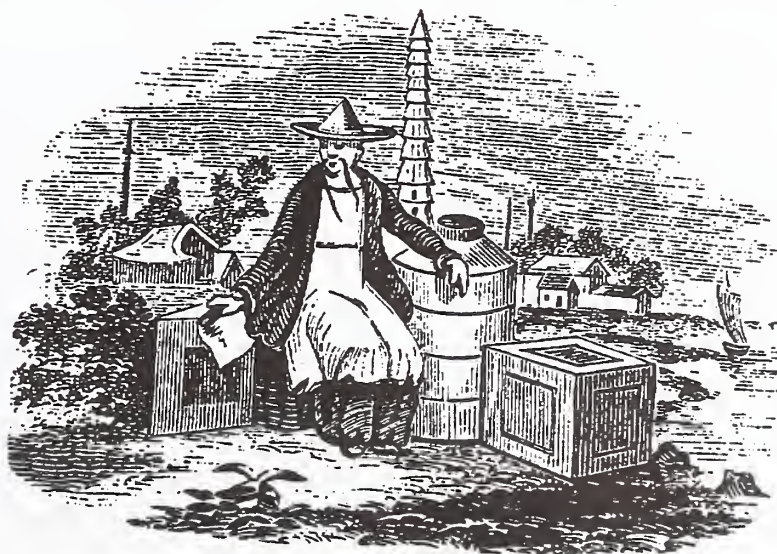
Theories on the causation of malaria had been legion. Most everyone recognized that swamps were somehow central to the enigma of malaria; but from that point on the etiologic speculations diverged. Some contended that the disease came from drinking swamp-water, perhaps some ill-defined toxin [Linnaeus, in his doctoral thesis sub-

scribed to this notion.] Others were persuaded that climatic heat, undoing the balance of the internal humors, was the root cause. Most observers, however, believed that the cause was to be found in the breathing of some nocturnal effluvium, some invisible vapor, a miasma, which had arisen from the marshes [hence the Italian term, malaria, meaning evil air.] Those advocating this causative theory were called 'miasmatisists.' A vocal minority contended that it was a water-borne bacterial disease much like typhoid fever. And then there were those who offered outrageously bizarre proposals. For example, there was a Washington obstetrician, Dr. Albert King, whose name survives marginally for two reasons:

first, he was in the Ford Theater audience on the night that Lincoln had been shot and was one of the physicians who attended the president until his death. And second, he had published a paper claiming that malaria was not carried by the night air but by the mosquito.

The answer to the first question, the biological identity of the causative agent, was finally provided by a scholarly and most unmilitary French army surgeon named Laveran.

Charles Louis Alphonse Laveran, son and grandson of distinguished army surgeons, was born in Paris in 1845. He attended the imperial military medical school in Strasbourg and then served briefly as a junior military





surgeon in the Franco-Prussian War [mostly as a prisoner of war.] He then was assigned to Val de Grace Hospital as a lecturer in military medicine.

His meticulous lectures culminated in an acclaimed text on military epidemiology which was published in 1875. In a notable chapter on telluric diseases [Latin, *tellus*, pertaining to the earth], Laveran approaches the malarial fevers as an exercise in classical logic. After an exhaustive review of the world's literature on the geographic distribution of malaria, he defines the general nature of the causative agent. He observes, first, that while malaria is closely associated with the tropics, there are sufficient numbers of cases arising in cooler climates; and, alternatively, there are many tropical lands, such as New Caledonia, absolutely free of malaria. Thus, he contends, the cause cannot be, by itself, excessive heat. He notes, too, that swamp fever may prevail despite the absence of swamps. For example, the disease frequently arises when canals are under construction or when there is massive

movement of earth, something that he refers to as engineer-made malaria. And since the malarial peril extends well beyond bodies of still water [marshes, swamps, canals, moats] and distal to the prevailing winds, the "seeds" of malaria must then be wind-borne.

Laveran states also that the malarial agent tends to hover close to the ground since dwellers in upper stories of buildings are at measurably less risk than those who live on the ground floor, and furthermore that intervening forests act as barriers which protect communities from malaria. He concludes that malaria is caused by an airborne agent capable of propagating itself, an organism best generated in the warm, still waters of a swamp.

Five years later while working as a military surgeon in Algeria, he treated a 24 year old artillery gunner suffering from acute malaria. Knowing that there is much blood destruction during the course of acute malaria, Laveran elected to examine the young soldier's blood under the microscope. And on

November 6, 1880, he visualized the living organism of malaria. Perhaps there had been others who had seen these parasites within the red blood cells of malaria victims, but Laveran was the first who knew what he saw, and knew too the critical implications of his chance observation. He named his novel organism *Oscillaria malariae*, since it was flagellated and wiggled incessantly. Protozoologists have since renamed the genus *Plasmodium*, with numerous species. It is part of a larger family of pathogenic protozoa that cause a variety of intestinal, neurologic and blood-borne diseases including sleeping sickness and amebic dysentery.

Twenty five years later Laveran was awarded the Nobel Prize for his insights into the cause of malaria. In the 27 intervening years since his inaugural paper, yet another army doctor [Surgeon-Captain Ronald Ross] provided the answer to the second basic question when he discovered the active carrier of the disease, namely the female *Anopheles* mosquito; and numerous Italian scientists including Golgi, Marchiafava and Celli then clarified the complex life cycles of the *Plasmodium* parasites, sexual and asexual, both in the mosquito vector and in the human host.

By exploiting the biological limitations of both the parasite and the insect vector which transmits it, much of the temperate world has now been freed of the scourge of malaria. The last European pocket of endemic malaria, in Macedonian Greece, was cleared by 1975. But each time another war or civil conflict erupts, public health interventions to drain swamps, spread insecticides, and undertake other preventive and curative measures break down. Despite the fact that malarial control, even eradication, is now feasible, the World Health Organization still reports an average of 380,000,000 new cases of malaria each year.

— Stanley M. Aronson, MD

☞ A Pediatric Perspective on the RIte Care Program ☞

Patrick M. Vivier, MD, PhD, and Anthony J. Alario, MD

While national health care legislative reform efforts failed during the 1990s, individual states have been establishing programs to address the conflicting needs of controlling health care costs while at the same time expanding access to the uninsured. One approach has been to transition Medicaid from fee-for-service to a managed care model, using the resulting savings to expand eligibility. Rhode Island is in the forefront of this movement, with the establishment of RIte Care in 1994. This paper reviews the pediatric experience under RIte Care.

RIte CARE: A PROGRAM DESCRIPTION

Currently all Medicaid beneficiaries in Rhode Island are enrolled in RIte Care, except the elderly, disabled and children in foster care. In addition, pregnant women with family incomes below 350% of the Federal poverty level and children (initially up to the age of six years but subsequently extended up to 18 years) with family incomes below 250% of the Federal poverty level, have been defined as newly eligible.¹ Average enrollment in the program is just over 70,000; approximately three quarters are children; 21% have a primary language other than English. (See article by Tricia Leddy, this issue).

RIte Care is administered by the Rhode Island Department of Human Services, which contracts with four managed care organizations (MCOs) to provide a defined package of services for a monthly capitated rate. Three of the MCOs had been in operation prior to the formation of RIte Care. One (Harvard-Pilgrim Health Care of New England) is a staff model HMO that has operated in the state for many years as well as a network of office based physicians. The two others (United HealthCare of New England and

BlueChiP Coordinated Health Partners) offer services through a network of providers, including office based physicians, hospital based clinics and community health centers.

The financial relationship between these MCOs and their providers includes fee-for-service and at-risk arrangements. The fourth MCO (Neighborhood Health Plan of Rhode Island) was formed specifically to participate in RIte Care and is primarily composed of the state's 14 community health centers.

In each of the MCOs, the RIte Care beneficiary selects or is assigned to a primary care provider within three weeks of enrollment. RIte Care's primary care providers practice in four different practice settings: office practices, staff model HMO, community health centers and hospital based clinics. The financial arrangements between MCOs and their primary care providers vary. However, in all cases the primary care provider has case management responsibilities. Authorization is required for additional services, such as referral to specialists and emergency department visits.

A PRIMARY CARE APPROACH

The American Academy of Pediatrics (AAP) has called for all children to have a "medical home" and other experts have emphasized the importance of primary care as the foundation of the health services system.^{2,3} A key aspect of RIte Care is its primary care approach, with a special emphasis on prevention. All children have a defined primary care provider who is responsible for providing a broad range of health services, consistent with the AAP definition of a medical home. Patients and primary care providers have an explicitly stated relationship:

Abbreviations Used:

AAP	American Academy of Pediatrics
HMO	health maintenance organization
MCO	managed care organization
WIC	Women, Infants and Children Program

the provider is responsible for the child's comprehensive health care needs and the patient understands that there is a single source of care available to them. For both patients and providers, this is a major improvement over traditional Medicaid programs.

On the patient side, RIte Care gives low income families access to what their more economically advantaged counterparts have generally already had: a pediatrician, family physician or other provider whom they can identify as "their" doctor. This person (or group) accepts responsibility for meeting their health care needs, regardless of the type of problem or day of the week. Under RIte Care providers must offer accessible, comprehensive services and must arrange around-the-clock telephone coverage. Many recipients have chosen office-based practices as their medical home. While this has always been an option under Medicaid in Rhode Island, increased reimbursement rates under RIte Care have made participation by private physicians more economically feasible. Many recipients have remained with public providers (community health centers and hospital based clinics). These sites have augmented their strengths (e.g., translation abilities, a sensitivity to the needs of the poor, lead poisoning treatment and WIC nutritional programs, etc.) with a greater focus on being true primary care practices, rather than walk in clinics. This has meant expanding after hours phone coverage and addressing emergency department utilization.

As for providers, under RIte Care

they now have a defined panel of patients. Though patient panels are always in flux, as patients change providers or lose RIte Care eligibility, at least at any moment in time providers know who their patients are. Physicians with stable private practices in the suburbs may take having defined patient panels for granted. However, under fee for service Medicaid, many hospital based clinics, community health centers and other inner city providers had great difficulty identifying which patients truly saw them as their doctor and which ones used them as one of a number of options. The clear delineation of patient panels allows for outreach. For instance, providers can identify, and target, newborns who need well child care or preschoolers who have fallen behind on their immunizations. This complements the use of computerized tracking systems at the state level (Kids Net), as well as by individual providers.

Defined patient panels also provide exciting possibilities for research and quality assurance. This should allow providers to learn more about their practice patterns within RIte Care and will allow researchers to study fundamental issues in the delivery of primary care. Since RIte Care is funded under a federal 1115 demonstration waiver, the program included from the start a number of assessment strategies. In addition, research focused on RIte Care is underway at Brown University un-

der a Robert Wood Johnson grant. These assessment projects can improve our understanding of the delivery of primary care to low income populations so that we can better meet their needs.

NECESSARY BUT NOT SUFFICIENT

While patient panels and defined responsibilities are a step forward, they do not guarantee that children will have an ongoing relationship with a primary care provider. When the provider-patient relationship is defined by the insurer, in this case RIte Care or the individual MCO, the provider-patient relationship can end if, or when, the patient's insurance status changes. A loss of insurance or change in carrier can sever the relationship with the primary care provider. This is a significant draw-back to managed care as a whole, but is particularly salient in the Medicaid population. The RIte Care program guarantees coverage for 6-month intervals, but this doesn't eliminate the problem of disenrollment. Furthermore, some MCOs participating in RIte Care have set enrollment limits. If the MCO affiliated with the recipient's provider of choice is closed to new enrollees, the family must select another provider from a different MCO.

Beyond these bureaucratic limitations are the cultural and behavioral changes that both patients and providers must make in the primary care oriented, managed care model. For patients the new system is not as easy as the traditional fee-for-service

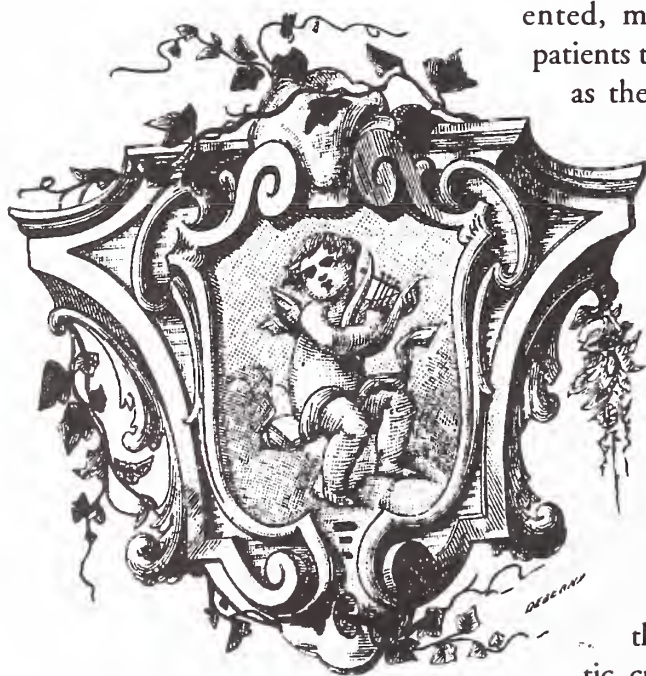
Medicaid program. Patients must actively choose a MCO and a specific primary care provider. They must also learn to seek out their primary care provider as the first contact for all but true medical emergencies. For many recipients, this is not a difficult transition (93% choose an MCO). However, for

those families facing linguistic, cultural or social barriers, the

process of choosing and maintaining a relationship with a single primary care provider may be difficult. Care must be taken to ensure that recipients can make this transition, without endangering the health of vulnerable children. This requires not only sensitivity at administrative levels, but also necessitates ongoing patience and teaching from the primary care provider as to how to obtain services in the new system.

Providers too must make major changes. Office-based clinicians who have not extensively worked with Medicaid recipients must consider the special needs of low income populations. Since the poor suffer disproportionately from diseases such as lead poisoning and tuberculosis, clinicians must adopt some clinical strategies that may not be routinely necessary for more affluent children. RIte Care patients may face access barriers that insurance coverage does not address: minimal fluency in English, belief systems that conflict with contemporary medical theory, and/or racism. Logistical barriers are also present: lack of transportation, lack of phone service and no money for over-the-counter medications. While making RIte Care patients indistinguishable from commercially insured children will gain them access to "equivalent care," equivalent care may not suffice. Consequently, special services have been built into RIte Care that are not generally part of commercial managed care plans; e.g., free bus passes, taxi rides for some visits and coverage of some over-the-counter medications..

The health centers and hospital based clinics that have served low income populations over many years have also had to learn a stronger primary care perspective and fiscal soundness that are integral to private pediatric practices. For most health centers and hospital clinics, this represents a significant reorganization: changes in fiscal management, increasing access (hours of operation, formal practice coverage plans, etc.) and a change in approach (reducing emergency department utilization, etc.). In a sense, the optimal service organization for RIte



Care children will combine the strengths of public providers and those of office based primary care practices; creating financially sound, well organized primary care practices that are sensitive to the needs of low income populations.

CARE COORDINATION OR GATEKEEPING?

Primary care makes sense as the foundation of the health services system.^{3,4,5} Most health needs of children can be managed in a primary care setting, including both well child and illness care. Further, the primary care provider can work with patients to make rational decisions regarding specialty services and coordinate those services. The benefits in terms of continuity and coordination of care justify the primary care approach, even beyond any cost containment that may be realized.

Rhode Island has been fortunate with RIte Care. This has not been the case in all managed care systems. Bureaucratic pressure to make rational use of specialty services (including emergency department use) can segue into rationing. The term "gatekeeping" is unfortunate. The emphasis must not be on primary care physicians or insurance companies preventing children from getting specialized services. Rather, the goal should be appropriate use of specialized services. Just as we do not prescribe medications that are inappropriate for a given problem, we should not make referrals that are inappropriate. However these decisions need to be made on clinical grounds, not short-term economic ones.

As with most aspects of RIte Care, information is not yet available to evaluate fully the use of specialized services. Emergency department visits have gone down while physician visits have increased - a positive sign that families are being given primary care alternatives that will hopefully be more satisfactory for them, will reduce overcrowding in the emergency department and will save money. However, care must be taken to analyze reductions in emergency department use. One study in Maryland found that more than

40% of Medicaid children who were denied approval for an emergency department visit were not evaluated by their primary care provider within one week.⁶ While the child improved in most cases (though no poor health outcomes could be documented), it is still disconcerting that for many children care was being denied, not transferred to a more appropriate setting. The emphasis in RIte Care has been on offering accessible primary care services and educating families regarding appropriate use of the emergency department. Providers, administrators and recipients must continue to develop strategies to ensure that appropriate use of services continues to be emphasized, not the denial of care.

The Rite Care program is an important innovation in the organization of health services for low-income families and the uninsured. More children are being included than was the case under traditional Medicaid and all recipients have a defined medical home to meet their health care needs.



As for the use of pediatric sub-specialists, RIte Care requires a referral from the primary care physician. However, contrary to American Academy of Pediatrics recommendations,⁷ in most cases the referral has to be approved by the MCO. This aspect of managed care rightfully concerns physicians and patients the most. Not only does it introduce new paperwork, it also means that patient management decisions can be taken out of the doctor-patient relationship and given to in-

surance bureaucracies. The primary care physician should be in the best position to judge the necessity of referral to a specialist and should be the one to make such decisions.

Under RIte Care the major referral difficulty has been the increased administrative demands involved in requesting approval from the MCOs. This can be a time consuming and frustrating process. There have also been some disruptions in established referral patterns. The major problems that we have experienced at Rhode Island Hospital have been with behavioral and developmental services. Limits have been placed on prior referral patterns, with the MCO reducing referral options and emphasizing the role of the school system in providing developmental services. One can debate the appropriateness of these policies, but regardless they place increased burdens on the schools, the primary care provider and the RIte Care families. Perhaps this example illustrates part of the adjustment that providers must make in developing more cost effective patient management strategies. However, it also demonstrates the uncomfortable reality that under a managed care system, primary care providers and patients do lose some control over health care decisions.

While the barrier to sub-specialty referral is a potentially major problem under a managed care system, under RIte Care it remains mostly a theoretical concern. In fact one pediatrician has described referrals under RIte Care to be "vastly improved" over the old Medicaid system. For the most part, the MCOs have included a broad range of pediatric sub-specialists in their plans and have been fairly liberal in approving these services. In some respects the RIte Care program has even broadened the range of referral options, as there is now access to all sub-specialists participating in the MCO as a whole - not just Medicaid providers. This allows primary care providers to maintain the same referral patterns for RIte Care as they use for their commercially insured patients.

In the early experience, care coordination has been the emphasis for RIte

Care, not gatekeeping. Providers and the MCOs need to continue to make adjustments as the program develops to ensure effective referral mechanisms. Protecting patient access to pediatric sub-specialty care may become a larger issue in the future if the managed care companies face greater financial pressures to decrease costs. In addition, if children with disabilities are folded into Rite Care in the future, current procedures may be inadequate, as those children will have much greater sub-specialty needs than the current Rite Care population.

CHALLENGES AND OPPORTUNITIES

The Rite Care program is an important innovation in the organization of health services for low-income families and the uninsured. More children are being included than was the case under traditional Medicaid and all recipients have a defined medical home to meet their health care needs. Prevention and primary care have been appropriately identified as the priorities, while still providing good access to more specialized medical services.

State government, MCOs, providers and recipients will need to remain vigilant and work to continue to improve the program. In particular, efforts must be made to ensure financial solvency. The participating MCOs have experienced financial losses; in at least one case this had led to a decrease in physician reimbursement rates. Some financial strains are to be expected in a new program and there are signs that the situation is improving, but care must be taken that the books are not balanced by cutting needed services or alienating providers. Insurers and providers must devise positive strategies for controlling costs while maintaining access. Perhaps even more challenging, the state must find ways to adequately fund the program into

the future. Insufficient funding will doom Rite Care. Since the majority of Medicaid expenses are for the elderly and disabled,⁸ cutting funds for Rite Care beneficiaries cannot solve the problem of spiraling Medicaid costs.

"Rite Care was developed to address the problems associated with limited access to primary and preventive care for low income families due to financial, cultural, language, knowledge, and transportation barriers." That has been the focus to date. If this remains the case and if the program receives adequate funding, the Rite Care program has great potential. If the "managed" part of "managed care" becomes emphasized and Rite Care becomes a vehicle for ratcheting down expenditures, the program will become a disaster. The managed care strategy is merely part of the approach to emphasizing primary/preventive care while eliminating wasteful expenditures. Rite Care has moved forward more rapidly and successfully than could have been expected of such a large transformation of the health services system. State government, MCOs, providers and recipients must continue to work together so that Rite Care can fulfill the promise it has shown in improving access to primary care and preventive services for low income children.

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RIte Care, Rhode Island's Medicaid Managed Care Program, provides comprehensive health coverage for Medicaid families and for uninsured pregnant women and children throughout Rhode Island. Administered by the Office of Managed Care in the Department of Human Services (DHS), RIte Care has dramatically changed and improved the way low-income families in Rhode Island receive health care. RIte Care now assures that most children in Rhode Island have access to comprehensive, quality health care coverage. Families select a health plan, as well as a primary care physician who manages their overall care. Participating health plans include United HealthCare of New England, Neighborhood Health Plan of Rhode Island, Harvard Pilgrim Health Care of New England and Blue CHiP/Coordinated Health Partners, Inc.

Until 1993, Rhode Island's Medicaid Program was a traditional fee-for-service program. For AFDC families, Rhode Island was first among all 50 States in per capita hospital expenditures and 49th in per capita physician expenditures. More than 50% of inner-city residents received their primary care in hospital emergency rooms. A strong network of community health centers provided primary care to 60,000 people each year, serving as a safety net to some of the State's 115,000 Medicaid participants and 100,000 uninsured. However, there was still limited access or no access at all to primary and preventive care for the majority of families on Medicaid.

RIte Care's goal is to improve access and quality of care for Medicaid families and uninsured pregnant women and children. It is designed to emphasize primary and preventive care, address language, cultural and transportation barriers to health care, and provide outreach and education. Over 75,000 Rhode Islanders are currently

enrolled; two-thirds of them are children under age 18.

RIte Care members receive almost all services through their health plan including physician visits, diagnostic services, hospitalization, pharmacy and other medical services. In addition, RIte Care health plans provide several non-traditional benefits including interpreter services, nutrition services, childbirth education programs, parenting classes, smoking cessation programs. Thanks to an agreement with RIPTA, bus passes, and taxi and van rides if necessary, are provided.

*More than 800 primary
care physicians
participate in the RIte
Care Program through
their affiliated health
plans—a dramatic
increase from the
approximately 350
primary care physicians
who treated Medicaid
families prior to RIte
Care.*



RIte CARE NOW INCLUDES CHILDREN UP TO AGE 18

On May 1, 1997, RIte Care was expanded to include uninsured children up to age 18 in families with incomes less than 250% of the Federal Poverty Level (FPL).¹ Prior to this, the program was limited to uninsured children up to age eight. With this expan-

Abbreviations Used:

DHS	Department of Human Services
FPL	federal poverty level
NICU	neonatal intensive care unit
RIPTA	Rhode Island Public Transportation Authority

sion, virtually all children in Rhode Island now have access to comprehensive health insurance coverage. Through January 1998, 2341 previously uninsured children have been enrolled since this most recent eligibility expansion began. Since the beginning of RIte Care in 1994, almost 10,000 previously uninsured women and children have been enrolled.

However, there may be up to 16,000 uninsured children in Rhode Island, most of whom are probably eligible for RIte Care. Because the perception lingers that RIte Care is a "welfare" program, a multi-faceted campaign, including posters, billboards, newspaper, TV, and radio ads, is underway to encourage working families with uninsured children to apply. DHS is also planning to simplify the application process with mail-in applications.

RIte CARE'S RESULTS

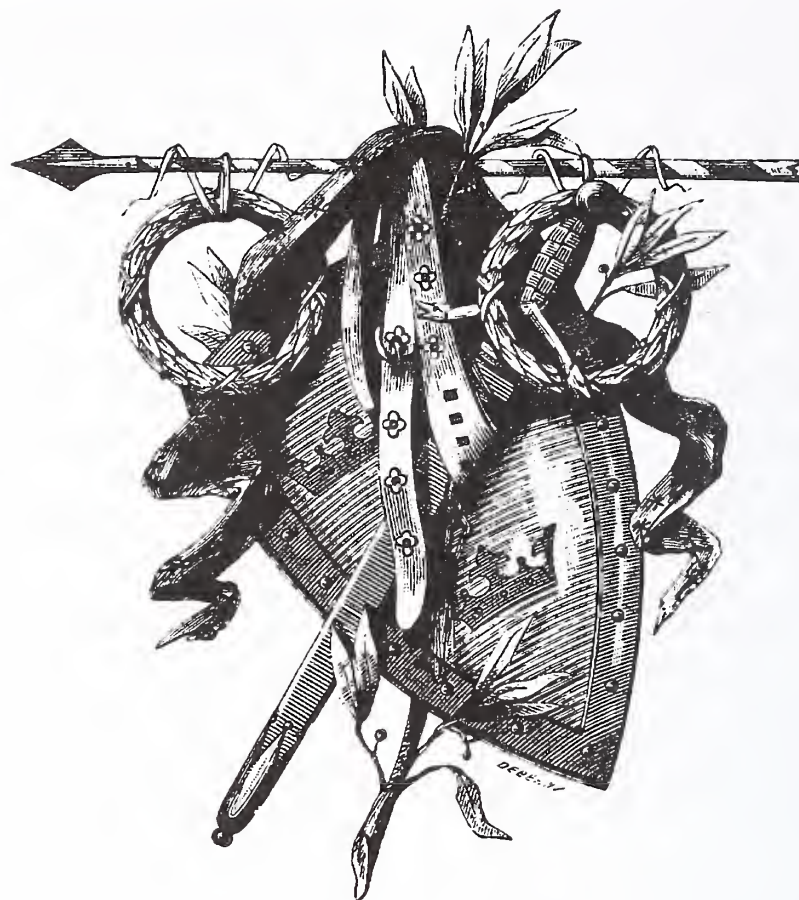
RIte Care's participating health plans and their physicians deserve much of the credit for the program's success. More than 800 primary care physicians participate in the RIte Care Program through their affiliated health plans—a dramatic increase from the approximately 350 primary care physicians who treated Medicaid families prior to RIte Care. Primary care physician visits for the average enrollee increased from two per year prior to RIte Care to five per year in RIte Care's first year of operation. During the same period, emergency room visits and hospital use decreased by more than one third under RIte Care.

RIte Care has had a positive impact on maternal health.² The number of women on Medicaid waiting at least 18 months between births increased from 58% pre-RIte Care (1993) to 72% after RIte Care's first year (1996), almost completely closing the gap between Medicaid and commercially insured women in Rhode Island. The percentage of pregnant women on Medicaid who smoked during pregnancy decreased significantly from 33% in 1993 to 27% in 1996.

RIte Care has shown significant improvements in prenatal care for participants. First trimester prenatal care increased from 76% in 1993 to 82% in 1995. Adequate prenatal care, as defined by an "adequate" number of prenatal visits and early entry into care, also increased significantly from 44% in 1993 to 69% in 1996.

RIte Care members show improved infant health outcomes. The number of low birth weight infants born to Medicaid enrolled mothers decreased from 9% in 1993 to 8% in 1996.

The Rhode Island Department of Health provisional 1996 infant mortality data indicates that Rhode Island's overall infant mortality rate declined to 5.5 deaths per thousand, the lowest it has ever been in Rhode Island. As RIte Care covers a third of Rhode Island's births, this success may in part be attributable to RIte Care.



Physicians should feel especially proud of the program's excellent member satisfaction. In a 1996 member satisfaction survey³, over 1000 RIte Care participants responded with resounding praise for the program. Ninety-five percent of the members expressed satisfaction with RIte Care. Ninety-six percent were satisfied with their primary care physician.

Finally, perhaps not most statistically significant, but certainly significant in a real way were the unsolicited testimonies written by survey respondents, praising their physicians and the access to needed services through RIte Care. Most poignant was the same unsolicited comment from four different mothers describing the program's impact on their children's lives and health—"RIte Care is a blessing."

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Implementing a Computer-based Mammography Education Project in a Managed Care Setting

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TRENDS IN MAMMOGRAPHY

Breast cancer has the highest incidence rate, excluding skin cancers, and the second highest mortality rate of all cancers in women.¹ It is a disease of older women: 50% of newly diagnosed breast cancer cases and 54% of mortality occur in women 65 and older.² Mammography has been shown to be the most effective strategy currently available to detect breast cancer at the earliest stage. Screening programs that include regular mammograms can reduce mortality 30-40% in women 50 and older.^{3,4} Yet mammography continues to be underutilized. In a 1994 nationally representative sample (National Health Interview Survey), 81.2% of women 50-75 reported ever having had a mammogram, while only 62.9% had a mammogram within the preceding two years and 45.5% had the exam within the preceding year (unpublished data). Furthermore, mammography use decreases with age.⁵

MAMMOGRAPHY IN MANAGED CARE ORGANIZATIONS

Managed care organizations have an additional incentive to improve mammography rates. Purchasers of health care plans increasingly use HEDIS criteria (Health Plan Employer Data and Information Set), a standardized measurement process of the National Committee for Quality Assurance (NCQA), an organization that accredits its managed health care plans.⁶ HEDIS measures offer purchasers a way of evaluating and comparing HMOs. By voluntarily participating in HEDIS, health plans can meet some requirements of the NCQA, as well as meet purchasers' needs for comparable data on quality of care. HEDIS reports the percentage of women ages 52 to 69 who have received a screening mammogram during the preceding two-year period.

MAMMOGRAPHY INTERVENTIONS IN HMOs

Managed care organizations have designed some mammography interventions to address both patient and physician barriers to screening. Managed care members generally have no access barriers of cost, or not knowing where to go for a mammogram. Nevertheless, results of these HMO-based interventions have been mixed.

Trock et al.⁷ compared mammography rates of HMO members who received a patient education program to a comparable non-HMO control group. The program included health education packets, mailed reminders, a physician letter, and counseling calls. Screening rates were 40% higher in the HMO group than in the control group, but the benefits were not equal for all patients. Screening rates improved significantly for women with low incomes, but not for those with higher incomes. The effect also was not as strong among black women. King et al.⁸ targeted HMO members age 65-74 who, despite free mammograms, brochures, and reminder letters from their physicians, were overdue for a mammogram. These women were randomized into one of three groups: 1) no intervention; 2) telephone counseling; and 3) telephone counseling plus a physician letter. Women in groups 2 and 3 had higher screening rates than those who received no intervention (13% for no intervention; 27% for phone counseling; 32% for phone and letter). Still, the majority of these overdue women did not have a mammogram.

Taplin et al.⁹ found that a letter from a woman's primary care physician did not improve the likelihood of her

Abbreviations Used:

CATI	computer-assisted telephone interviewing
HEDIS	Health Plan Employer Data and Information Set
HMO	health maintenance organization
HPHC-NE	Harvard Pilgrim Health Care of New England
NCQA	National Committee for Quality Assurance

receiving a mammogram compared to a control group (46.8% vs. 45.6%). An additional follow-up reminder card did increase the likelihood. Burack et al.¹⁰ found that patient reminder letters had little effect on mammography participation, and the effect of physician reminders varied by physicians' practice site.

Davis et al.¹¹ randomized women overdue for a mammogram into three groups: 1) a birthday card reminder only; 2) a personalized letter from the medical director along with educational materials; and 3) a phone call incorporating a screening reminder, counseling on barriers to screening, and the opportunity to schedule an appointment. Women in group 3 were most likely to receive a mammogram (28%), compared to the birthday card group (15%) and the letter/educational materials group (9%).

MAMMOGRAPHY EDUCATION PARTNERSHIP

Results from projects in HMOs are modest. One reason may be that reminders and standard educational materials did not address differences in individual women's knowledge and attitudes toward mammography, and ultimately, each woman's "readiness" to make a behavior change. Researchers at the Center for Gerontology and Health Care Research at Brown University, in conjunction with Harvard Pil-

grim Health Care of New England (HPHC- NE), have received funding from the National Cancer Institute to explore approaches to motivate women to get mammograms on a routine schedule. The objective of the Mammography Education Partnership has been the development of breast cancer screening interventions utilizing a public health approach that minimizes cost and maximizes outreach.

The Mammography Education Partnership based its interventions on the Transtheoretical Model of Behavior Change,¹² which proposes that people differ in their readiness to adopt a health-related behavior and go through a series of stages as a natural part of reaching and maintaining a healthy behavior. The stages include: Precontemplation (presently not doing the behavior and not intending to start); Contemplation (not doing the behavior but considering initiation); Action (has initiated a change); and Maintenance (has sustained a behavior change). A woman's readiness for mammography is determined by asking about her past history and her future intention for following through with the desired behavior. Interventions that use the Transtheoretical Model are tailored to an individual's readiness to adopt a behavior.

INDIVIDUALIZED TAILORED MESSAGES

Tailored, individualized messages have been shown to modify smoking, diet, and exercise. Interventions using tailored messages typically have depended on the expertise of highly trained professionals and have occurred within the confines of a medical office. Staff to patient ratios have been low; the time invested per patient has been intensive. In contrast, public health campaigns, which can reach large numbers of people at a lower cost, have traditionally used standard educational messages without regard to differences in participants' readiness to adopt the behavior. The "one size fits all" approach is clearly less effective. However, responding to individuals has required staff-intensive programs.

The Mammography Education

Partnership extended tailored mammography education messages to large numbers of women outside the context of a medical visit through an "expert system" computer program. Expert systems had been developed to address other health behaviors, including smoking cessation.¹³ An expert system uses data about an individual to generate personalized written messages. Data can be collected about a patient's medical history, sociodemographic characteristics, and attitudes about risk factors and medical technology (in our case, mammography). The program is called an expert system because it implements logical decision-making rules developed by experts and selects educational messages from a "library" of choices, generating personalized letters or tip sheets.

The technology allows for sophisticated, individualized health education materials which can be grounded in well-accepted theories of behavior change. Further, expert systems can reinforce the physician's message to any number of patients, independent of a visit to a medical office, yet based on personal patient data - information that normally would be available to a provider during an office visit. An expert system based on the Transtheoretical model can generate messages that acknowledge stage of readiness and provide explicit behavioral strategies and motivational messages to move patients along the continuum of readiness to adopt a behavior change. Prior to the Mammography Education Partnership, an expert system had never been designed for mammography.

CENTRALIZED RECORD KEEPING SYSTEM

The introduction of a computerized expert system into a managed care setting has great potential, in large part due to the centralized record system of a staff model HMO. Unlike the traditional indemnity plan in which patients have a separate medical record with each provider, the staff model HMO compiles one unified, system-wide patient record. Even if an HMO member has an out-of-plan medical visit, results are reported back to the HMO. All medical visits and test results are docu-

mented. Therefore, there is the potential to track not only what actions the patient has taken, but also what actions the patients has not taken. For a group model or an Independent Practice Association (IPA) model HMO, similar information about medical visits and tests can be collected through the claims system.

MAMMOGRAPHY EDUCATION PARTNERSHIP

The Mammography Education Partnership has used an expert system in two different interventions. The first project, conducted between 1992 and 1996, was designed to test whether mammography rates could be improved by using educational materials that included an expert system-generated letter. Names of potential participants were provided by the HMO's management information system. A total of 1874 women aged 40 to 74 were randomly assigned to one of three groups: 1) No educational materials; 2) Standard mailed materials (not stage-matched); and 3) Stage-Matched mailed materials. At the start of the project, training was provided to the primary care providers on the assumption that they could influence screening behavior for any woman through office visits, without regard to group assignment. Data were collected from participants at four points in time using computer-assisted telephone interviewing (CATI). Surveys included questions about general attitudes toward mammography and specific barriers to screening, sociodemographic characteristics, and relevant medical history.

The mailed materials for the Standard group were the same for all women. Included were tips on preventive medical visits, advice on the three-part plan for breast health (mammography, clinical breast exam, breast self-exam), and a question and answer sheet about mammography. Women assigned to the Stage-matched group received a packet designed specifically for their stage of readiness as determined by their answers to the baseline interview questions. For example, women who were not considering having a mammogram received basic information about the process and

benefits of mammography, while women who were having regular mammograms received suggestions for remembering to schedule a yearly mammogram.

Women in the Stage-matched group also received a letter generated by the expert system. The letters had four sections: 1) recognition of her stage of readiness, including supportive quotes from women in the same stage; 2) comments on benefits of mammography; 3) strategies for progressing to the next stage or maintaining action; and 4) motivational ideas from women in the same stage. A key to creating letters is to choose the most appropriate text from the pool of messages: predefined values or "cut-points" guided the selection of motivational paragraphs. Women who scored below a cut-point received messages to encourage more action. Women who scored higher received reinforcing messages to continue their positive behavior.

The percentage of women who received mammography was higher for the Stage-matched intervention group compared to the No educational materials group (manuscript under review). The Standard intervention group had screening rates between the other two. Therefore, it appears that stage-matching made the difference.

The second study, currently underway, is designed to explore reminder strategies to motivate women to get repeat mammograms, which is the ultimate goal of mammography education. As with the first study, the HMO provides names of potentially eligible women. Interview data are collected using a Computer Assisted Telephone Interviewing (CATI) system. Women are randomly assigned to one of four groups: 1) Telephone interview with educational intervention materials mailed two months after having a mammogram; 2) Telephone interview with educational intervention materials mailed 10 months after having a mammogram; 3) Mailed postcard reminder 10 months after having a mammogram (no educational materials); and 4) Self-select group (woman chooses among groups 1, 2, and 3). Personalized, stage-matched letters are generated by the

expert system for women in groups 1 and 2. Women with sociodemographic characteristics and personal barriers to screening that indicate a risk of not having a mammogram receive a counselor telephone call. The intervention will continue until spring 1998.

Breast cancer screening programs that include regular mammograms can reduce mortality between 30 and 40% in women 50 and older. Yet mammography continues to be underutilized.



Tip sheets are generated in response to a survey question asking a woman what might prevent her from getting a mammogram in the future. For example, if a woman mentions fear of radiation, she will get a tip sheet explaining the minimal risk of low-dose radiation, and the standards required of mammography machines, facilities, and personnel. Eighteen barrier tip sheets have been developed, including cost, fear of finding cancer, no symptoms of breast cancer, no family history of breast cancer, embarrassment and discomfort.

BENEFITS OF TAILORED INTERVENTIONS USING AN EXPERT SYSTEM

Mammography interventions using an expert system have some distinct advantages over office-based interventions. First, for a provider to deliver an effective personalized message about mammography, it is necessary to wait until a woman has a medical visit. An expert system intervention can be designed for those women who visit a provider, but also for those who do not. A phone interview or mailed survey can collect the information to generate the personalized letters. Therefore, it provides a strategy to reach those patients who avoid contact with the medical sys-

tem.

Second, with office-based interventions, providers must devote time to implement intervention protocols. Given the limited time of office visits, it is difficult for providers to cover all issues surrounding mammography, particularly during an acute care visit. Furthermore, even if mammography is addressed, it is impossible for a provider to question each woman about all her opinions about screening, and then respond to them. An expert system can generate messages reacting to a range of attitudes as a complement to the limited behavioral counseling that can be conducted in the office. Also, as a woman's attitudes change over time, materials can be modified. In fact, the system can be programmed to comment automatically on a change in attitudes or behavior.

A significant benefit of a centralized record keeping system is that a time commitment of busy front-line providers or staff is not required for the logistics. Activities such as identifying or recruiting patients, collecting patient data, or tracking behavioral actions can be accomplished through the use of computer systems.

LIMITATIONS OF THE EXPERT SYSTEM INTERVENTIONS

A limitation of tailored interventions is their practicality outside of the research setting, or without additional funding. The start-up costs for an expert system can be high. For example, an expert knowledgeable about the Transtheoretical model (or another theoretical model) is required. In addition, a health educator is needed to translate the theory into consumer-friendly messages, and a computer programmer is needed to design the system. There are also the costs of the requisite hardware and software. However, once the "shell" of an expert system has been developed, it can be adapted for interventions with other behaviors.

Another consideration is the information needed for the expert system. If the education materials are going to address attitudes, this information must be collected. However, medical records do not include comprehensive informa-

tion about attitudes. Collecting data through telephone interviews can be expensive and time consuming. Alternative methods of data collection include scannable mailed questionnaires and computer-assisted surveys completed by patients in the waiting room.

FUTURE OF MAMMOGRAPHY INTERVENTIONS IN MANAGED CARE ORGANIZATIONS

Although the rates on a national basis for women who have had a recent mammogram are increasing, rates for repeat mammograms remain low. Therefore, future interventions in HMOs will need to address the barriers to screening for women who are not having repeat mammograms on the recommended schedule. Interventions such as the one developed by the Mammography Education Partnership may help determine the most effective ways to personalize strategies to remind women to schedule their next screening.

Expert systems integrated with centrally located medical records allow identifying and contacting women with specific characteristics. For example, as women who maintain a regular schedule have more mammograms, there will be a greater chance of false positive results. A woman's attitude toward future mammograms can be impacted significantly by this experience. Also, as each woman has a longer mammography history, barriers that can interfere with future exams will become more specific to her personal experiences. Interventions addressing barriers due to past experiences (i.e. callback for repeat mammogram without further testing; suspicious mammogram leading to biopsy and then normal results) could be particularly helpful during the time between mammograms.

The interventions described in this paper have targeted patients primarily, using data from telephone interviews to generate tailored written materials. But this information was not entered in the patient's medical record. The benefits of including this data in the medical file can also be explored. This could provide the physician with helpful information about behavioral readiness,

attitudes, and barriers.

Achieving greater adoption of regular mammography will require addressing women's individual circumstances and barriers to screening. A HMO is in a unique position to extend the provider's reach in an individualized way to large numbers of women. Integration of a data-based strategy such as an expert system into the patient care protocol of the HMO can further improve mammography screening rates.

NOTE: Examples of the expert system letters and tip sheets are available from Beverly Ehrich, MPH.

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An internist is not necessarily a geriatrician. A family practitioner is not necessarily a geriatrician. Yet these physicians care for older adults. What is different about being a geriatrician? How is geriatrics practiced in an HMO? To go from the usual practice of medicine to a "geriatric" model requires significant change. Harvard Pilgrim Health Care is introducing clinical geriatrics to their primary care physicians by teaching geriatric assessment. My thesis is that this type of change can be done most easily in a managed care system, but that resulting models can be applied to other systems. The most basic change is going from a pathophysiological approach alone to one that includes a functional assessment. The functional assessment identifies otherwise overlooked problems, can be a way to design special programs for this population, can save money, and can increase patient satisfaction. This paper describes the Harvard Pilgrim Health Care (HPHC) system, the development of the screening assessment and its implementation. This approach gives the health plan information to plan for its population of elders.

THE "GERIATRIC IMPERATIVE"

The first question is: "why bother?" Some refer to the growing number of elderly as "the geriatric imperative." This population is expected to more than double by 2030. Life expectancy is now 76 years; soon it will be 82 years. Care of older patients accounts for more than 50% of the practitioner's time; the elderly make 25% more visits to the doctor than younger patients; and older patients are the major utilizers of the acute care hospital. Older patients often have multiple interacting diseases. They have decreased functional reserves to meet the acute exacerbations of these diseases. Neil Resnick of Harvard

Medical School calls this the "homeostenosis" of the elderly. Looking at function through geriatric assessment instead of dividing the patient into diseases allows the clinician to identify early or critical areas that point to serious illness. For example, a patient with sepsis may simply have a decrease in ability to walk or lack of appetite rather than a spiking fever or chills. It is therefore important to know that person's functional baseline in order to draw appropriate conclusions.

FIRST SENIORITY

In 1995, Harvard Community Health Plan launched First Seniority, a Medicare risk contract plan for seniors in Massachusetts and Rhode Island. In a "risk contract" the plan receives a lump sum payment each month; this is 95% of what Medicare paid for the average fee-for-service beneficiary in a specific geographic area. This lump sum includes hospital care, durable medical equipment, skilled home health care, medical care (primary and specialty) and skilled nursing home care. There are presently approximately 60,000 First Seniority members in Massachusetts, Rhode Island, Maine and New Hampshire. Initially the members of First Seniority were cared for by staff model physicians; this continues to be the case in Rhode Island as of February 1998. When Harvard Community Health Plan merged with Pilgrim Health Care and became Harvard Pilgrim Health Care (HPHC), patients of IPA (Individual Practice Associations) and Joint Venture physicians in the community joined the plan. A geriatrician was hired to set policy and design special programs for this population. The question guiding the program forma-

Abbreviations Used:

CME	Continuing Medical Education
ENT	ear, nose and throat
ER	emergency room
FTE	full time equivalent
HEDIS	Health Plan Employer Data and Information Set
HMO	Health Maintenance Organization
IPA	independent practice associations

tion was: How does the clinical management approach to an 80 year-old differ from the approach to a 40 year-old?

EMPHASIS ON FUNCTIONING

Some insight to this question can be gained by a personal perspective. I was an internist in private practice at a non-teaching hospital for eleven years; a geriatric conference changed my perspective on care for the elderly. Geriatrics offered a radical shift of attitude from that traditionally found in internal medicine. The emphasis in geriatrics was on assessment of function, or the impact of disease on people's daily lives, rather than on disease alone. I began to include screening geriatric assessment in my routine office practice. It provided me with new knowledge about my patients and saved time in the long run. The format I initially used was developed by Aging 2000, a grassroots organization committed to improvement of care for the older adult. When I joined HPHC in 1994, I continued to work with older patients. However, I could go farther since HPHC was introducing principles of geriatric care to both patients and primary care physicians.

The American Geriatric Society and the National Committee on Quality Assurance strongly support the use of functional assessments within managed care organizations. The American Geriatrics Society recommended that managed care companies "provide

appropriate clinical geriatric competencies for health care providers" and "appropriate utilization of functional and health related quality of life outcomes,"¹ The National Committee on Quality Assurance has set functional assessment as one of the HEDIS 3.0 (Health Employer Data Information

Set) criteria for HMO "report cards." Baseline evaluations using the SF-36, a self-report health status questionnaire, will be done in 1998. In 2000 the same beneficiaries will be restudied for evidence of stability or change in function. Several studies show the need for educational efforts directed to

physicians. In one study, internists failed to recognize 66% of the identified functional disability problems in their patients.² In another, geriatric assessment identified previously unrecognized abnormality in 55% of patients assessed.³

DEVELOPING A GERIATRIC ASSESSMENT PROGRAM

The first HPHC conference on geriatrics was held in the spring of 1995. It introduced 300 primary care doctors to functional assessment and geriatric syndromes. The Medicare Education Partnership was soon formed. This took the First Seniority program and combined it with an academic arm, the Department of Ambulatory Care and Prevention, a department that works closely with Harvard Medical School and runs a Primary Care Internal Medicine residency at the Brigham and Women's Hospital in Boston. An offshoot of this group was the "Geriatric Assessment in Primary Care Working Group," which met during early 1996. This group of internists, geriatricians, nurse practitioners and consultants on quality monitoring and teaching developed the current recommendations for geriatric screening and assessment.

The traditional "Comprehensive Geriatric Assessment" takes 3-4 hours. The patient is seen by a physician, nurse practitioner, social worker, and often by a physical therapist, pharmacist and neuropsychologist, or psychiatrist. However, there have been successes and failure with these interventions. Conducting a comprehensive assessment on frail hospital inpatients did not show a major difference in outcomes compared to the control group.⁴ A study done at Rhode Island Group Health involving 200 outpatients who were assessed by a geriatric team showed that only about 50% of the recommendations made by the team were followed by the primary care internist.⁵ A meta-analysis of 28 controlled studies showed that programs "with control over medical recommendations and extended follow up were more likely to be effective."⁶ Two studies showed significant improve-

TABLE 1 – SCREEN / INTERVENE

1. Medication Evaluate all medications for dose and appropriateness	Consider lower dose, d/c, compliance aids, pharmacist evaluation
2. Mobility Have you fallen all the way to the ground in the last 12 months? Do the "Get up and Go test" (get up from a chair, walk 10 feet in 15 seconds)	Consider physical therapy consult, home safety evaluation
3. Mentation Ask the person to remember 3 objects	If misses even one, do the Folstein Mini Mental State Exam; lab tests for reversible causes of dementia; consider neurology consult
4. Activities of Daily Living Ask about higher level functions such as shopping and finances and if unable, basic functions like eating and dressing	If a deficit, refer to social service, case management, or community resources
5. Social support Ask "Who would help you if you became ill?"	See #4
6. Advance directives/Living will Ask: "Do you have an advance directive or living will?"	Initiate discussion; give patient information; suggest family discussion
7. Hearing Occlude one ear and either rub fingers by the other ear or whisper numbers or "boxcar"	Consider ENT or audiology referral
8. Vision Test ability to read at 20/40 or to read newsprint	Consider referral to optometrist or ophthalmologist
9. Incontinence Ask "Do you find yourself wet unexpectedly?" (women) or "Do you get up more than twice a night to urinate?" (men)	Consider urology referral
10. Nutrition Ask "Have you lost more than 10 pounds in the last six months?"	Administer the nutrition screen, ¹⁰ medical workup
11. Depression Ask "Do you often feel sad or depressed?"	Administer the short form of the Yesavage Geriatric Depression Scale; ¹¹ consider mental health referral; antidepressants

ment in several parameters after outpatient assessment. In one study, those patients who had had a geriatric assessment and had to be admitted later to the hospital had a marked decrease in length of stay there.⁷ In another, patients were on fewer medications after the intervention, had improved depression scores, and had a decreased rate of hospitalization.⁸

What emerges from a review of this literature is the importance of continuity in who performs the assessment and who follows up on its implementation. Based upon our reading of this literature, the HPHC working group unanimously decided that the best person to do the assessment was the primary care doctor.

Philosophically, HPHC (and before it Harvard Community Health Plan and Rhode Island Group Health Association) has always been a strong advocate of the key role played by the primary care physician. Therefore the total number of geriatricians employed by the plan at this time is only 0.5 FTE. HPHC decided against employing geriatrician consultants in favor of enhancing the knowledge and skills of primary care physicians. In the same way that every internist and family practitioner is a diabetologist or cardiologist, every internist and family practitioner is a geriatrician.

Our next questions were: What would the geriatric assessment look like? Could a doctor in a busy practice conduct this kind of comprehensive assessment? In keeping with our setting, our working group chose to develop and implement a SCREENING geriatric assessment. This concept had already been explored by Moore in terms of sensitivity and specificity of screening questions and physical examination.⁹ The next task was to select clinically relevant domains that were essential. After much debate, we decided on eleven domains. For each, we either asked a screening question or did a screening examination and, when a problem was identified, recommended an intervention. Screens and associated interventions are listed in Table 1. A priority was made only with the first three domains,

which we all believed the most important.

With a model in place and support from HPHC, how were we to introduce this approach? There has been increasing interest in new ways of changing the behavior of doctors other than traditional lectures. Oxman looked at 102 studies of CME. He found no impact with printed material alone; effectiveness of conference was increased if there was "practice" within the session, effectiveness of outreach visits was high, as were audit and feedback. The strategy that resulted in the greatest change in professional performance was multifaceted.¹² Looking at improving drug therapy decisions, Avorn introduced the concept of "academic detailing." He applied the methods of pharmaceutical representatives and analyzed their effectiveness in changing physician behavior. The method that resulted in sustained change in behavior at nine months was one that combined glossy printed material and several face to face encounters.¹³ The Working Group began planning for this approach to bring screening geriatric assessment to the 3,000 internists and family practitioners in the Harvard Pilgrim Health Care system.

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IMPLEMENTATION OF THE PROGRAM

The effort began in early 1997 with the mailing of a laminated pocket guide with the eleven domains and a brief "screen-intervene" explanation. This was followed by conferences at hospital Grand Rounds and at educa-

tional meetings attended by groups of physicians at IPAs, and staff model centers. While this is not the one-on-one approach used in academic detailing, it does require speaking to small groups. This lecture format was combined with other modalities. A professionally produced video showed the ease of the assessment in real time. The video is accompanied by a manual that describes the rationale for each domain, gives a detailed description of further tests and questionnaires, and lays out specific intervention strategies. There is a self-test to send in to the Medicare Education Partnership for CME credit. The "education" phase, while it really never ends, is slated to move into the implementation phase in 1998. It usually takes about eight minutes to screen a patient. Almost all of the eleven screens can be done by a non-physician, either a medical assistant, nurse, nurse practitioner or physician's assistant. Follow up on "positives" takes longer, but other members of the team or referral to a specialist might be appropriate once the basic geriatric problems have been identified. One busy clinician uses a "rolling assessment" where he spreads the eleven domains over a year as patients return for check-ups related to chronic problems.

Follow up to the initial teaching modalities will be undertaken using various means. Physicians will be asked to submit a summary sheet of "pass"/"fail" of the eleven domains. This will alert the health plan to problems in their population, and may alert the individual practice to the need for case management. As a part of data collection for research, we will be able to track function over time. HPHC is recommending that all their primary care physicians do the screening assessment on new 65 year old patients and again annually. Practice standards may be set as they are in other quality of care areas, such as immunization rates. Practices will be given comparative feedback on their rates of return of the summary sheet since this will serve as the primary data collection and monitoring tool. A newsletter will note different implementation strategies. One practice currently faxes this assessment

to all sites of care - i.e. the ER, the nursing home and to the home care agency. The screening assessment is brief and easy to transmit and read. I use it in the ER to evaluate functional status, particularly for cross-coverage patients whom I have not seen before. All interns in the Lifespan medicine track are being trained to use this assessment for every nursing home patient seen as part of the HPHC geriatrics teaching.

CONCLUSION

A coordinated system opens up exciting opportunities in geriatrics. A recent editorial states "...HMOs are ideally positioned to institute systematic approaches to managing common geriatric syndromes. Practice guidelines adapted by integrated medical groups or staff-model HMOs can be effective in encouraging aggressive secondary prevention while protecting elderly patients from iatrogenic overtreatment."¹⁴

For a clinician, the most important outcome is not research or data collection, but improved care for patients. A coordinated system is a good place to start with this approach. The primary care physician is ideally situated to be the leader in this endeavor. Teaching and use of the screening geriatric assessment can bring geriatrics to the primary care physician.

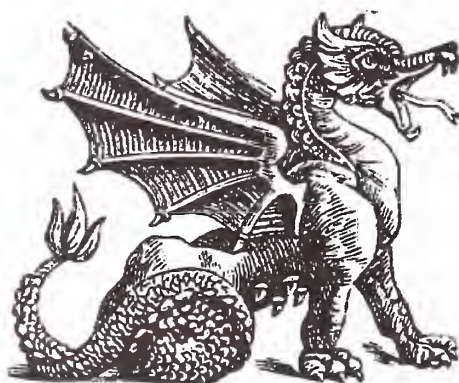
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The Impact of Managed Care on Chronic Care Agency Providers

Susan M. Allen, PhD, Mary Fennell, PhD, and Linda Laliberte, JD, MS

We live in a time of uncertainty, as the debate rages around future directions for health care policy. In the absence of consensus, health care system change proceeds at a frightening pace. What is least clear in this paradigm shift from fee-for-service to managed care is how people with chronic health problems, and the community-based organizations that serve them, will fare. What is the place of chronic care agencies in a managed care world that emphasizes prevention and primary care? Do the features of a managed care delivery system fit with the needs and preferences of the chronic care population?

There is an increasing recognition that the "medical model" of diagnosis, treatment, and cure that has dominated our health care delivery system throughout this century is ill-suited for people for whom cure is not a possibility, but who may live a full life with their chronic health problems. A different model of care is called for when the goal of preventing death is replaced with the goal of managing life with a disabling condition. Regular medical care, both primary and specialist, is important in maintaining health status and treating acute episodes. However, medical care is only one of a broad array of needs, which may also be social, emotional or rehabilitative, and may vary widely among individuals with the same diagnosis.

How large is the population of people with chronic care needs? While estimates vary with different definitions and methodologies, results from a national survey indicate that there are more than twelve million people in the United States today who need either human or technical assistance to perform routine daily activities (e.g., bathing, dressing, cooking, housework). Most (approximately 80%) live in the

community.¹ Since the majority of conditions that cause disability increase with age, we can expect the number of people with disability, and thus the number of people requiring supportive services (formal and/or informal), to grow. In fact, while people age 65 and older now make up 13% of the U.S. population, that percentage will climb to 20% by 2030 as the baby boomers reach retirement age. Furthermore, the sub-group aged 85 and older is projected to grow most rapidly.²

Services required by individuals with chronic health problems may include nursing care, homemaker services, physical therapy, occupational therapy, mental health services, and respite care. The agencies which provide these services, together with medical care providers, constitute a community-based system of care for people with chronic health problems. However, to the extent that the term "system" implies cohesion and integration, it is a misnomer. Our health care system is highly fragmented and has traditionally been dominated by hospitals reimbursed by both public and private health insurance systems. Thus, community-based service agencies are the "poor relatives" of established health care providers. The advent of managed care has not changed this focus.

Drawing on information collected during site visits to both acute and chronic care providers as part of the Robert Wood Johnson Foundation-funded "Springfield Study of Populations with Disabilities,"³ we discuss the impact of managed care and larger health system change on chronic care

Abbreviations Used:

CMA	Community Medical Alliance
FFS	fee-for-service
HMO	health maintenance organization
MCO	managed care organizations
PACE	Program for the All-inclusive Care of the Elderly
PCC	primary care coordinators
VNA	Visiting Nurse Association

agencies, as well as on their clients.

WHERE DO COMMUNITY-BASED SERVICES FIT IN A MANAGED CARE WORLD?

Our interviews with key players in the health and social service system of Springfield, MA, conducted in 1994, revealed a system in the midst of change. Few interviewees felt that their organizations had stabilized. In fact, there was an undercurrent of apprehension about the implications of actual and impending change for the role of their organizations in the evolving system of health care delivery. Corporate mergers were predicted, contemplated, and discussed with the sentiment that one had better "get on the bandwagon" to survive.

Administrators and providers pondered the potential "niche" (a word we heard often) for their organization in the changing landscape, dominated by competing systems of managed care. Agency providers often cited affiliation with emerging systems and/or diversification as the key to survival. Agencies that ignored impending change and the wisdom of being "positioned" to fit whatever form system change would take were seen as "endangered species".

An example is Springfield's major home care service providers, the Visiting Nurse Association (VNA) and an Area Agency on Aging that administered both state and Federally-funded

programs for the frail elderly. Although VNA administrators asserted that "we would probably like to continue to be independent and to function the way we have been functioning," they felt that a merger, or "affiliation," was inevitable. Area HMOs were increasingly incorporating home health agencies into their systems, effectively limiting or eliminating VNA access to HMO members. Affiliation discussions were underway with Baystate Medical Center, the area's largest hospital which, together with several HMOs under its corporate umbrella, was emerging as the city's dominant system of health care delivery. The VNA's decision not to affiliate with the city's second hospital, Mercy Hospital, had already resulted in a loss of referrals from this source. The VNA did subsequently affiliate with Baystate.

We also talked to the administrator of a large private home care agency who keenly felt the intense interagency competition that characterized the pool of home care agencies in the Springfield area. Her agency's response was to develop special teams and care paths for people with specific conditions. By offering high quality care to specific groups of high service users at a competitive price, her agency hoped to attract coveted contracts with managed care organizations (MCOs).

The Area Agency on Aging home care agency was negotiating with Mercy Hospital to become a PACE (Program for the All-inclusive Care of the Elderly) site, modeled after On Lok Senior Health Services in San Francisco. However, the agency voiced concern about their need to diversify to accommodate the health-related needs of the increasingly frail elderly people who maintained community residence, bolstered by an array of in-home services and adult day care.



Later, we learned that the proposed affiliation with Mercy Hospital did not happen. Since both State and Federal funding for home-based services has declined, this safety net provider worried about its ability to continue to meet the growing needs of Springfield's elderly. It may be that providers who operate at the margin will not easily fit within a managed care world.

Do the features of a managed care delivery system fit with the needs and preferences of the chronic care population?



What are the consequences of such strategic actions for agency clients? First, both the affiliation and specialty-niche strategies lead to greater fragmentation of the overall system, in which access to services for those with chronic care needs may be constrained by MCO system boundaries. Alliances with specific health systems and MCOs and resulting inability to cross system lines imply greatly diminished opportunities for consumer choice and autonomy. The overall system within the local community becomes less integrated, both functionally (in terms of financial, human resource, and informational management) and clinically (in terms of activities at the same stage of care delivery, as well as across different stages of care). Although both strategies are pursued to increase chances of short-term organizational survival, each strategy incurs long-term risk for the community care provider, and has the potential for even greater fragmentation of chronic care than was the case in a fee for service (FFS) system.

MANAGED CARE AND THE CHRONIC CARE CLIENT

Massachusetts began enrolling Medicaid beneficiaries into a managed care program (called MassHealth) shortly before our first round of site

visits to Springfield in 1994. However, not all people with high health service needs were enrolled at that time. Those invited to enroll had the option of appealing and remaining in the traditional fee-for-service Medicaid program. Nevertheless, many people with chronic health problems switched from FFS to managed care Medicaid along with the "general" Medicaid population.

The consensus of our informants is that MassHealth has increased access to care in the sense of increasing the pool of providers who are willing to serve the Medicaid population. Few primary care physicians in the Springfield area accepted Medicaid patients prior to the implementation of managed care, citing inordinate amounts of detailed paperwork as a disincentive. However, many of Springfield's primary care physicians were recruited to participate in MassHealth as primary care coordinators (PCCs). Medicaid beneficiaries were invited to choose a primary care provider from the provider pool, which also includes 8 HMOs. Thus, although MassHealth is not yet capitated, some Medicaid beneficiaries with chronic health problems are experiencing capitation as HMO members.

The philosophy underlying managed care is intuitively sensible, suited both to control health care costs (preventing illness is obviously cheaper than treating it) and to maximize the health of the population (avoiding illness altogether is clearly desirable). However, the question arises as to how people with complex health problems, who are historically high users of health care services, and who require a broad range of supportive and rehabilitative services to maintain community living, will fit with this philosophy of health care delivery.

On a positive note, MCOs are integrated systems, with far fewer bureaucratic hurdles than is typical in traditional FFS systems. Coordination mechanisms tend to be formalized, with little allowance for professional ideology to obstruct appropriate referral from one service to another. Results from the Medical Outcomes

Study comparing primary care performance for people with chronic illness in FFS versus prepaid plans found staff model HMOs to have significantly better coordination than FFS or network model MCOs, as assessed by both patients and participating providers.⁴ However, staff model HMOs scored lowest on service comprehensiveness.

While home health services are generally incorporated into MCO systems, they are for post-acute, not supportive care purposes. Medical care is of the primary care variety, with a limited number and type of specialists available for more complex health problems. Further, access to specialists is screened by primary care physician gatekeepers. It is a system structured for the typically well individual, who may have occasional, short-lived health problems but who generally is an appropriate target for MCOs' emphasis on primary prevention.

People with disability may benefit from a primary prevention model; however, due to their "thinner margin of health," secondary prevention of disability is a more pressing need, requiring a different set of services. Personnel associated with Springfield's Medicaid program were enthusiastic about increasing access to the city's physicians. While improved access to primary care is hypothetically an MCO bonus for disabled populations, there is the likelihood that chosen or assigned physicians will be unfamiliar with the complex health problems that characterize the most vulnerable of these populations. This possibility was confirmed by one Springfield informant who was a spokesperson for the disabled, and who had heard complaints from several people who had been assigned new doctors. Familiarity can make a difference: people with AIDS had lower mortality when cared for by primary care doctors experienced with the management of AIDS.⁵

Some clients with chronic health problems may be separated from their specialists, who may not be participants in Medicaid managed care. A middle-aged man with paraplegia complained that a switch to managed care would

totally disrupt the network of specialists he had worked so hard to construct. Further, the possibility that both primary care and specialty care physicians will transition in and out of MCOs raises issues of discontinuity in care for a population whose need for continuity of providers surpasses that of the general population.

Do MCOs underserve people with health problems? While competition among health plans has contributed to the growing emphasis on patient satisfaction, an outstanding question is whether or not mainstream MCOs will accommodate the disabled population. The potential financial losses from high-service users make them a risk in the risk-averse MCO culture. One advocate warned that the physician-as-gatekeeper feature of both capitated MCOs and fee-for-service MCOs that operate with primary care case managers can be frustrating as well as dangerous to chronic care consumers. A gate keeper who is unfamiliar with an individual's health problem can inadvertently deny or delay access to a service or specialist that may offset a client-perceived impending crisis.

Although little evidence exists on this issue, a study of home health care under FFS and HMO plans revealed that Medicare beneficiaries enrolled in HMOs were provided fewer visits and fewer personal care services. Home health under HMOs had a more strictly medical orientation, while FFS plans were closer to the medical/social/rehab approach appropriate for people with chronic health problems. Finally, adjusting for case mix, investigators observed a dose/response relationship between volume of visits and positive patient outcomes (i.e., stabilization and improvements in health status and functioning), suggesting that denying or offering a lower volume of services has consequences.⁶

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IS CAPITATION FEASIBLE FOR HIGH SERVICE USERS?

Capitation is not an unattractive feature of health care plans for people with chronic health care needs.^{7,8} It allows flexibility in custom designing services. However, realistic risk-adjusted capitation rates are essential for this approach to be feasible.⁹ Capitation must be accompanied by features that remedy all the shortcomings reviewed here: comprehensive service availability, including both core social and rehabilitative services as well as "satellites" of specialized services relevant to select populations; high levels of service integration and coordination, including close coordination between primary and specialty medical care to ensure prompt response in crisis situations; and substantial opportunity for consumer choice and control.

One successful model of managed care for the chronically ill is the Community Medical Alliance (CMA), a capitated risk-adjusted system for people with severe disability. CMA employs a team approach to care, consisting of a nurse practitioner and primary care physician, who provide primary care and ancillary services in the patient's home. The nurse practitioner serves in the dual role of case manager and clinician, maintaining close contact with clients to avert medical emergencies. Nurse practitioners develop close collaborative relationships with clients. Comparison of utilization patterns of CMA enrollees and comparable clients of Medicaid FFS indicate substantial cost savings attributable to redistribution of costs from hospital and specialty services to home care and primary care.¹⁰ Thus, a comprehensive, custom-tailored, system of community-based care for even the most disabled members of the population may achieve system goals of reduced costs while also maximizing consumer autonomy in defining needs and choice in determining the means to meet those needs.

PROSPECTS FOR THE FUTURE

Shortell and colleagues forecast a new stage of evolution for our health care system: the transition from orga-

nized delivery systems into community health care management systems.¹¹ In this delivery system, fragmentation is replaced by an integrated and coordinated system of public health, clinical, and management services focused on the complete continuum of care. Hospitals will lose (and to some extent, have already lost) centrality as the hub of such integrated systems. In particular, the coordination of care for the chronically ill and/or disabled will come from the home health agency working with the primary care physician.

Our study in Springfield suggests how community-based service providers in one moderately-sized community have responded to changes in both the acute care and the home health industries. Unfortunately, we have not yet made that transition into the community health care management system. Restructuring and reorganization of the acute care system have not proven to be the integrative boon many writers had predicted for relatively healthy populations, let alone for the chronically ill. Although integrated community health systems imply coordination and integration of care for the chronically ill through the leadership of primary care providers and home health agencies, at present we see a very different picture taking shape. Rather than claiming leadership, many of the service providers for these vulnerable populations are instead still reeling with the uncertainty produced by changes designed to reduce costs in the acute care system, and with the need to "deal with" the proliferation of managed care systems. Indeed, their survival may depend on their ability to "get on the (managed care) bandwagon".

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The Emergence of Medicare Managed Care:

Implications for the Post-Acute Sector

Vincent Mor, PhD

THE RISE OF MANAGED CARE

Over the past decade a revolution has been underway in the US health care financing and delivery system. Fee for service insurance is giving way to a variety of managed care arrangements, and a majority of non-elderly Americans with private insurance are members of Managed Care Organizations (MCOs). With market penetration exceeding 50% in many communities, capitated managed care is rapidly overtaking cost-based, fee-for-service payment as the dominant reimbursement paradigm for the American health care system (Group Health Association of America 1993). The dominance achieved by MCOs in the private insurance market is being replicated in the public sector. Medicare HMO members accounted for 8.5% of all 36.4 million Medicare beneficiaries nationwide in 1994 (Hoechst Marion Roussel 1996). However, there are regional differences. For example, after experiencing a 128% increase in enrollees over the previous year, HMOs accounted for 20.7% of the Philadelphia region's Medicare market in 1995. In Los Angeles, HMO penetration in the Medicare market exceeds 50%, and in California over 25% of the Medicare population is enrolled in Medicare risk contract MCOs. In many other markets MCOs are competing aggressively to enroll seniors, often using enriched coverage and benefit packages that include prescription drugs as incentives.

Managed care also has emerged as an answer to state governments' struggle to contain costs. While there are many detractors, states are carefully examining the experience in Tennessee, where all Medicaid recipients (the poor and medically indigent such as

most seriously chronically ill and aged) were transferred from the state's fee for service system to MCOs responsible for all health care under a single monthly, per capita rate. Other states have implemented mandatory transfers of their poor families and children, who, although numerous, consume relatively small proportions of states' Medicaid dollars. Several states have petitioned the federal government for permission to undertake a similar wholesale transfer of individuals with government-supported insurance (Medicare & Medicaid) to MCOs. Enrollment in Medicaid managed care rose 31.3% between 1994 and 1995; as a result, 28.7% of Medicaid recipients were enrolled in some type of managed care program. Current debates in Congress about reducing Medicare expenditures to avoid the system's impending bankruptcy center on the increased use of MCOs in spite of the absence of concrete evidence that Medicare beneficiaries will join them or that they reduce aggregate Medicare expenditures.

Changes in financing have precipitated changes in delivery systems, particularly among hospitals where occupancy rates have been dropping pre-

Abbreviations Used:

HMO	health maintenance organization
MCO	managed care organizations
SHMO	social health maintenance organization

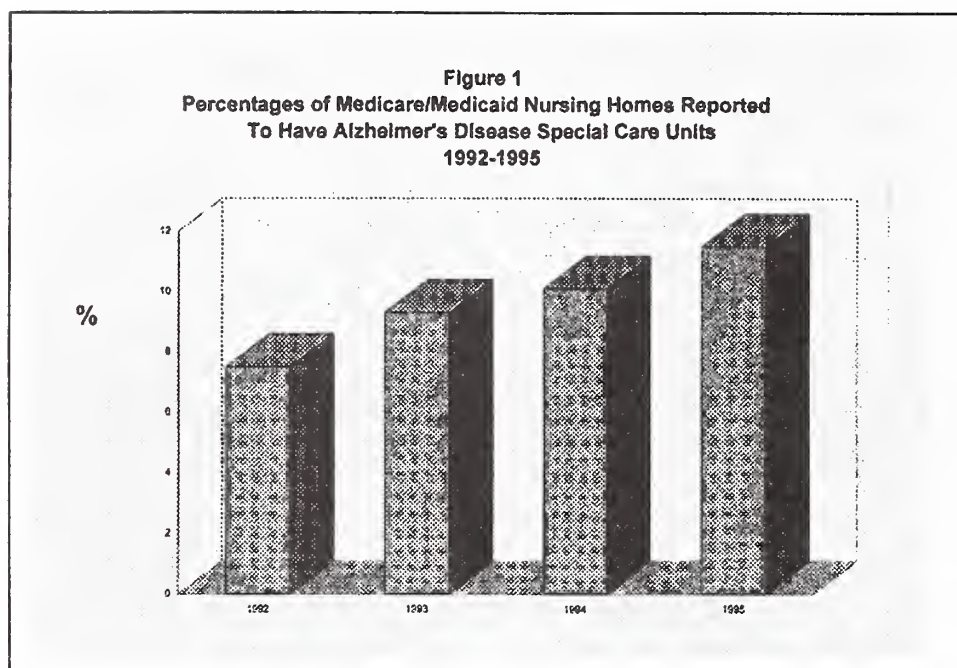
cipitously. Mergers and acquisitions of hospital beds among not-for-profit hospitals have led to reductions in total hospital beds; nevertheless, occupancy rates in most markets are below 70%.^{1,2} The relationship between physicians and hospitals has also changed; some physician plans operate separately while others align themselves with hospitals providing the primary care coverage base for hospital referrals.³

Nursing homes and home health agencies, still largely bound to the Medicare and Medicaid cost based, third party reimbursement systems, have also begun to change both in anticipation of future changes in reimbursement, as well as in response to continued reductions in length of acute hospital stays and increasing patient acuity. Many of these providers have developed specialized post-acute services serving patients still requiring intensive medical services outside the hospital, at least partially in order to compete for managed care contracts.

Table 1. Distribution of % Residents with Medicare coverage within Nursing Homes

	% of Residents					
Distribution	1987 ⁽¹⁾	1989 ⁽¹⁾	1991	1992	1993	1994
Mean	1.35	7.90	7.67	8.10	8.85	10.63
(S.D.)	---	---	19.28	19.81	20.72	22.63
Median	---	---	1.32	1.80	2.33	3.42
90 th Percentile	2.90	18.40	13.42	14.29	15.15	19.13
95 th Percentile	4.60	32.20	49.30	50.00	66.67	84.20
Sample Size	---	---	15,832	15,921	15,966	16,213

⁽¹⁾ Reported in personal communication from J. Zinn, Temple University



THE EMERGENCE OF INTEGRATED DELIVERY SYSTEMS

Integrated networks of providers representing the acute, ambulatory, and post-acute spectrum have formed in response to MCO penetration in the market place.⁴ These networks often arise from mergers and acquisitions or by "virtual" contracting.⁵ Recent qualitative data from the RWJF "Health System Change Tracking" project focused on the relationship between physician groups, hospitals and insurers. Less attention has been devoted to the mechanisms for integrating acute and long term care. While there have been ex-

amples of such entities for nearly a decade now, they have not been dominant players in the managed care world.

Vertically integrated health care systems are a composite of hospital, outpatient clinic and physician offices, home care and nursing home providers, and have the potential for integrating the care patients receive from many different sources. However, there is precious little empirical data to document the extent to which this potential is actualized. Over the past decade some HMOs have initiated innovative programs to manage the complex

medical and social needs of frail elders. The geriatrics literature is replete with reports of such experiences in selected locations across the country. Indeed, the Social Health Maintenance Organizations' (SHMOs) experiences of the 1980s and the more recent PACE demonstrations were structured to provide for the integration of acute and long term care services and medical and social services, either via organizational linkages or fiscal incentives such as capitation. The success of these efforts in controlling costs, improving certain measures of quality outcomes such as avoiding nursing home placement, hospitalization and aggressive medical care use, has been difficult to document.^{6, 7, 8, 9}

PURPOSE

We examined the changing role and structure of nursing homes in the US over the first half of the current decade in order to document the growing heterogeneity of these long term care organizations in response to MCO penetration. Using a comprehensive data set that characterizes all nursing homes in the country that are certified to serve Medicare or Medicaid patients, we tracked changes in the mix of reimbursement sources, the emergence of different types of special care units that serve specialized populations and changes in the skilled nursing needs of the residents. Comparable data are collected for every year, from all facilities in the country, consolidated into a single, longitudinal and comprehensive file which is the source of these data.

INCREASES IN MEDICARE PATIENTS

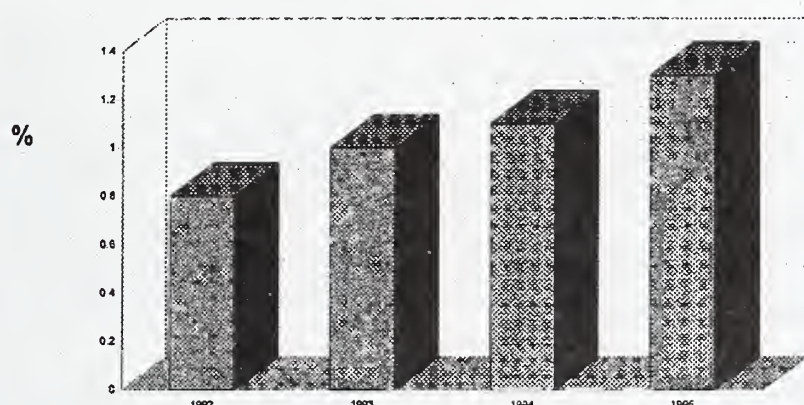
Medicare payments to nursing homes are only for skilled care (a continuation of the care that would otherwise have been provided in the hospital). (Table 1) There has been nearly a 10 fold increase in the average percentage of nursing home residents paid for by Medicare on any given day between 1987 and 1994. What is even more apparent is the growth in the concentration of homes that focus on Medicare patients. The home at the 95th percentile of the percent Medicare dis-

Table 2
Changes in Skilled Care Patient Needs and Sub-Acute Special Care Units 1992-1995

	Year				
	1991	1992	1993	1994	1995
Patients on Respiratory Therapy					
% of home with any	70.4	72.3	74.6	71.9	81.1
Ave. % of patients	4.2	4.5	5.0	5.9	6.6
Patients on IV or Blood Trans.					
% of homes with any	13.4	14.5	15.5	18.6	21.4
Ave. % of patients	1.1	1.2	1.3	1.5	1.8
Patients Tube Fed					
% of homes with any	70.0	71.2	72.3	77.5	78.6
Ave. % of patients	4.4	4.1	4.5	5.6	6.4

Source: OSDM/HCFA Medicare/Medicaid Automated Certification Survey (MMACS) files from April in each year

Figure 2
Percentages of Medicare/Medicaid Nursing Homes Reported
a Hospice Unit
1992-1995



tribution had only 4.6% Medicare patients in 1987, whereas by 1994 nearly all (84.2%) of their patients were covered by Medicare. Even in 1996, 30% of all homes had not a single Medicare patient, and in over 90% of homes Medicare patients accounted for less than 20% of the patient population.

SPECIALIZATION

Nursing homes adopt special care units to serve a particular population. Figure 1 reveals an enormous increase in the proportion of facilities reported to have a unit specializing in the treatment of persons with Alzheimer's disease. There are many forces behind this trend, but one has been the desire to attract patients' families able to pay for nursing home care privately for loved ones suffering from dementia. The availability of a specialized unit clearly is perceived as a sign of quality since homes with these units have significantly higher proportion of their residents being paid privately.

Hospice Units are another special service that remains rare but has been growing. Figure 2 shows nearly a doubling in the proportion of nursing homes purporting to provide hospice care between 1992 and 1995. Other special care units include dialysis unit (.45%), a disabled children's unit (.44%), a head trauma unit (.46%) and a rehabilitation unit (.45%). Altogether, 15.8% of all US nursing facilities in 1995 reported having some type of special care unit and over 300 facilities had multiple units.

Nursing homes and home health agencies, still largely bound to the Medicare and Medicaid cost based, third party reimbursement systems, have also begun to change both in anticipation of future changes in reimbursement, as well as in response to continued reductions in length of acute hospital stays and increasing patient acuity.



CHANGES IN PATIENT SKILL NEEDS

With the increase in Medicare post-hospital patients who need highly skill care, particularly due to shortening hospital stays, the acuity level of nursing homes has increased substantially. (Table 2) The average proportion of patients needing tube feeding has increased as has the proportion of homes with any one such patient. Similarly, the average proportion of pa-

tients on respiratory therapy rose to nearly 5% in 1995 and the proportion of homes with at least one such patient rose to over 80%. Again, we observe a pattern of concentration such that the top 1% of homes have 50% or more of their residents on respiratory therapy, meaning that they specialize in this type of care. While most facilities still do not relish the idea of serving patients needing routine blood transfusions, the proportion of homes with any such patients has nearly doubled in 5 years.

SUMMARY AND IMPLICATIONS

It is highly likely that the patterns observed in the first half of the decade will continue. Diversification in the nursing home sector, and in the long term care sector altogether, is likely to increase at a rapid pace. This process is clearly fueled by managed care and increased payment for highly technical skilled nursing services, at least partly because these skilled recuperative functions are being taken from the hospital.

The management challenges with this path are considerable, particularly given the very low reimbursement rates and narrow operating margins of many facilities. Administratively it is very difficult to take an organization that has historically had a custodial mission and convert it into an active, therapeutic one. Even more complex is trying to cluster multiple, potentially philosophically different care missions under the same organizational umbrella. In an industry which is not characterized by great executive skill, the challenges will be considerable.

Competition from alternative long term care providers, the increased administrative complexity associated with a mix of pre-paid contracts and cost-plus reimbursement, and the new information requirements of federal and state regulators, certification agencies, and a potential multiplicity of managed care contractors place unprecedented pressure on administrators inexperienced in handling complex systems. This is borne out by recent analyses revealing that homes managed by the most experienced administrators

have higher occupancy rates, higher private pay and Medicare case-loads, and superior outcomes on several dimensions in spite of having a more complex case mix.¹⁰ This suggests that facilities without the administrative and financial resources to adapt to change will be left to serve the population of persons (Medicaid) least able to advocate for themselves.

Nursing homes have historically operated in a stable, if not particularly munificent, environment, that posed few environmental threats. Competition among facilities was limited by the barrier to entry erected by Medicaid reimbursement policies and by regulations designed to control nursing home bed supply. While substitutes for nursing home care have always been available, inadequate public financing made them unaffordable for most individuals, reducing the potential competitive threat to nursing homes.¹¹

It is likely that the facilities that will fail under the intense competitive pressure will be those serving high proportions of poor residents who cannot leave the home if the care worsens in response to cuts in revenue. Homes serving the highest proportions of Medicaid patients tend to be concentrated among proprietary facilities that are not part of chains. These facilities have the least resources to fall back upon, meaning that their residents are vulnerable if management miscalculates in the competition for resources. The lack of a safety net and a limited regulatory response to quality deficiencies create opportunities for the unpleasant fallout which often occurs with transformation in the industrial sector. However, in this instance the industry being transformed is responsible for the lives of our most frail and vulnerable population.

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Rhode Island Health Plan Program Summary

William J. Waters, Jr, PhD

A new Health Plan Program of oversight and disclosure is being implemented in Rhode Island. This program is based on the "Health Care Accessibility And Quality Assurance Act of 1996," Chapter 23-17.13 of the General Laws of Rhode Island. The legislation is a direct outgrowth of the work of the "Special Legislative Commission To Study Managed Care Plans And Their Impact On Patients' Ability To Make Choices Related To Their Health Care Providers," chaired by former Representative George Zainyeh.

Oversight and disclosure under this law apply to all Health Plans operating in Rhode Island. The law defines Health Plans as: "a plan operated by a licensed insurance company, or hospital, or dental or medical service plan or health maintenance organization, or a contractor that provides for the delivery of care services to persons enrolled in such a plan through: arrangements with selected providers to furnish health care services, and/or financial incentives for persons enrolled in the plan to use the participating providers and procedures provided for by the plan."

The Rhode Island Department of Health is responsible for the implementation of the Health Plan Act including:

- certification of all Health Plans in Rhode Island every two years,
- overseeing the accessibility and quality of health services provided by Health Plans in Rhode Island,
- ensuring that Health Plans fulfill their consumer disclosure requirements under the Act,
- investigation of complaints, and
- statistical analysis and reporting.

All Health Plans will be required to provide each of their subscribers with a Consumer's Guide developed by the Department of Health with input

from Health Plans, consumers, providers, and other government agencies. The Consumer's Guide provides general information about managed care; it is not specific to any particular Health Plan. The Consumer's Guide includes standard definitions of managed care terms. The Consumer's Guide also includes a list of mandated health benefits which must be provided by health insurance companies and health maintenance organizations in Rhode Island. The Consumer's Guide will help to orient Rhode Islanders to the expanding and evolving systems of managed care in the state. Among other key points, the Consumer's Guide cautions that the consumer may be responsible for paying the bill if the health service

Abbreviations Used:

HEDIS Health Plan Employer Data and Information Set

is not a covered benefit, if the service is provided by a non-participating provider, if a proper referral or authorization has not been received, or if the Health Plan deems that the service is not medically necessary.

All Health Plans in Rhode Island will be responsible to provide each of their subscribers with a standardized Disclosure Form each year. This Disclosure Form was also designed by the Rhode Island Department of Health with input from Health Plans, consumers, providers and other government agencies. The Disclosure Form will permit consumers to make item-by-

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item comparisons of various health plans. It will help consumers to understand the basic characteristics of their own Health Plan in a simple and straight forward fashion including covered services or benefits. The Disclosure Form also describes the consumer's rights with respect to confidentiality, protection from discrimination, second opinions, refusal of treatment, emergency care and provider directories. It answers such frequently asked questions as: how does the Health Plan review and approve covered services, and how is coverage renewed or cancelled? The Disclosure Form also indicates the method that the Health Plan uses to pay providers.

All Health Plans in Rhode Island will be required to report statistical information to the Department of Health. This information will cover the following areas of Health Plan operations: revenue and expenses, plan enrollment, complaints received, requests for prior authorization, appeals, and HEDIS indicators. HEDIS indicators measure: effectiveness of care, access/availability of care, health plan stability, and use of services. The Department of Health will analyze these statistical measures and provide the public with a side-by-side comparison of Health Plans on a periodic basis.

A Health Plan cannot exclude a professional provider solely on the basis of the type of degree or license of the provider, or lack of admitting privileges if such lack is due solely to the professional provider's type of license.



All Health Plans in Rhode Island must provide "due process" for professional (noninstitutional) providers (that is, physicians, dentists, optometrists and other individual health care professionals). The "Health Care Accessibility & Quality Assurance Act" is not "Any Willing Provider" legislation, but it does incorporate limited due process protection for professional providers prior to credentialing, during the credentialing process and with respect to changes in privileges. Before a new credentialing process begins, the relevant professional providers must be

notified in the newspaper or equivalent medium at least thirty days prior to the close of the Plan's application process. A Health Plan cannot exclude a professional provider solely on the basis of: the type of degree or license of the provider, or lack of admitting privileges if such lack is due solely to the professional provider's type of license. If the Health Plan denies a professional provider's application, the provider must receive written notification of all the reasons for the denial within sixty days of receipt of a completed and verified application. Further, the Health Plan shall afford due process to credentialed professional providers for all adverse decisions resulting in a change of contractual privileges.

The Rhode Island Department of Health will work with consumers, Health Plans, providers and other government agencies to review and refine the program to the mutual benefit of all concerned.

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Rhode Island Quality Partners, Inc.

Edward Westrick, MD

Health Care Quality Improvement in Rhode Island

Since this issue of *Medicine & Health/Rhode Island* is dedicated to Managed Care, I would like to share some current health care quality improvement activity in this arena - including some of the Health Care Financing Administration's (HCFA's) thinking on this matter as well as Rhode Island Quality Partners' (RIQP) activities in Rhode Island. Let me again invite other contributors to this column on health care quality improvement in Rhode Island.

Managed Care means different things to different people. To some providers, Managed Care means administrative hassles: prior approvals, denials, excess paperwork; and loss of autonomy. To others, Managed Care provides the opportunity to improve the health of populations, using the best methods from medicine and public health.

MEDICARE MANAGED CARE

Managed Care has come to the Medicare program in recent years. Managed Care Organizations (MCOs) contract with HCFA to assume the risk for the health services of their enrolled population. They receive a prospective payment based upon the expected costs of the health care services in that population during the contract period. This system of reimbursement is seen as a method for value purchasing, part of the new mission of HCFA. In the near future, Provider Sponsored Organizations (PSOs) will be able to participate in contracts. HCFA

encourages MCOs to work with Peer Review Organizations (PRO) in their states to improve quality for their enrolled Medicare beneficiaries.

In December, HCFA hosted the Tri-Regional HMO Medical Directors Meeting here in Rhode Island. This meeting included HMO Medical Directors, Carrier Medical Directors, and PROs from 16 states and territories: Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, West Virginia, Washington DC, Puerto Rico and the Virgin Islands.

Participants heard about Medicare Managed Care: A Tool for Public

Abbreviations Used:

HCFA	Health Care Financing Administration
HCQIP	Health Care Quality Improvement Program
HPHC	Harvard Pilgrim Health Care of New England
MCO	Managed Care Organizations
PRO	Peer Review Organization
PSO	Provider Sponsored Organizations
QISMC	Quality Improvement System for Managed Care
UHP	United Health Plans of New England

Health, HEDIS/CAHPS, Value-Based Purchasing, Quality Improvement System for Managed Care (QISMC), Medical Policy and Managed Care, and PRO Collaborative Projects. The Medical Policy presentation was given by Parker Staples, MD, Carrier Medical Director of Blue Cross/Blue Shield of Rhode Island. Dr. Staples explained

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how medical policy is developed by Carriers both nationally and locally. In addition, he demonstrated how the Carrier and the PRO are working together to improve diabetes care in Rhode Island. PROs presented projects to the HMO Medical Directors for their consideration as quality improvement projects. RIQP presented on Stroke Prevention. There were presentations on Diabetes Mellitus, Congestive Heart Failure, and Peptic Ulcer Disease.

The presentation on stroke prevention was designed to demonstrate the methodology of the Health Care Quality Improvement Program (HCQIP) and to develop interest among MCOs for doing stroke prevention projects. HCQIP methodology starts with community needs assessment, looks for evidence based process-outcome relationships and practice guidelines, develops measures of performance and interventions for improving performance among collaborators.

STROKE PREVENTION

Stroke is the third leading cause of death and shares many risk factors with coronary artery disease, the leading cause of death. These shared risk factors (hypertension, dyslipidemia,

diabetes mellitus, smoking) are modifiable, as are two important stroke-specific risk factors, atrial fibrillation and carotid stenosis. The evidence base supporting stroke prevention practices is amongst the strongest in clinical medicine. Respected practice guidelines have been developed by national specialty organizations. Performance measurement in this area has been under development for a few years now and there are known interventions for improving performance.

Currently, RIQP is collaborating with Harvard Pilgrim Health Care of New England (HPHC) and United Health Plans of New England (UHP) on a stroke prevention project targeting anticoagulation practices in atrial fibrillation. This is part of a 10-state effort to increase the appropriate utilization of warfarin in patients with atrial fibrillation, in the ambulatory setting. Future projects in stroke prevention would likely address anti-platelet therapy, atherosclerotic disease risk factor modification, and evaluation and treatment for carotid stenosis. Many of the HMO Medical Directors from the three regions were enthusiastic about such projects.

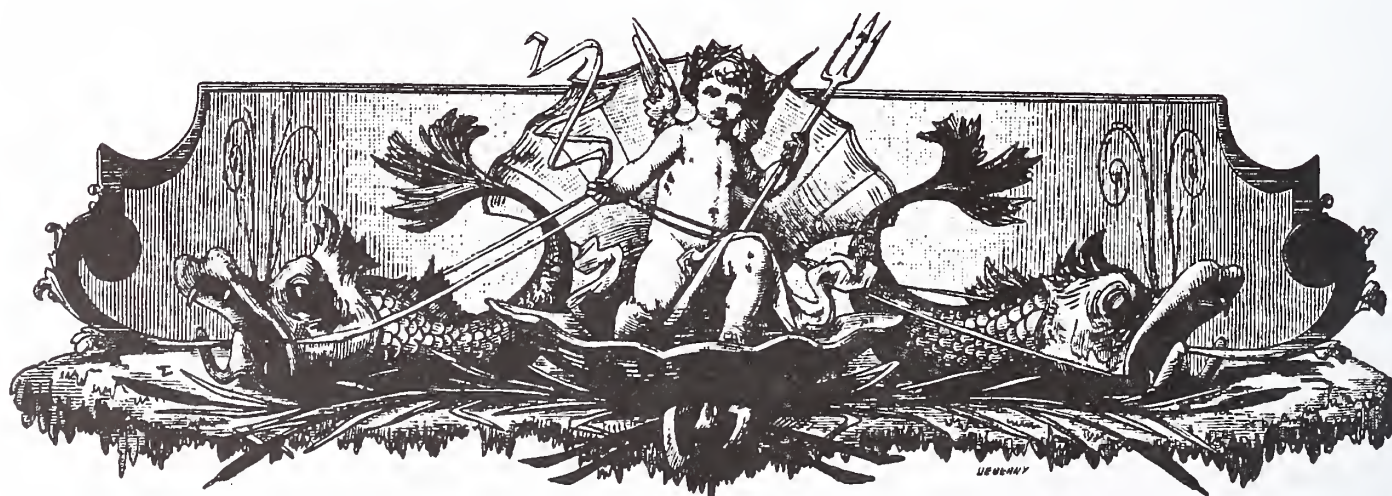
RIQP is working on other managed care based projects in diabetes mellitus, congestive heart failure, and myocardial infarction. The data on these and other projects will be shared through this column and other vehicles of communication. The confidentiality of performance data for collaborating providers will be maintained.

Please feel free to contact me about any of RIQP's projects.

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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Enrollment in HMOs in Rhode Island

Jay S. Buechner, PhD

During the 1990's, cost containment efforts by employers and government have spurred enrollment in managed health care plans, including health maintenance organizations (HMOs), preferred provider organizations (PPOs), point of service (POS) plans, and those indemnity plans that have adopted features of managed care plans, such as restricted provider networks, financial incentives on enrollees to use network providers, and more inclusive utilization review efforts. Of these variants of managed care, HMOs are the most well defined and identifiable category because of their relatively long history and the establishment of federal and state standards early in their evolution.

Nationally, the number of licensed HMOs rose from 572 in 1990 to 628 in 1996, or by 10%.¹ At the same time, the number of enrollees in HMOs rose from 33 million to 59 million, an increase of 78%. In Rhode Island during the same period, the number of licensed HMOs increased from three to five as one new plan was established in 1994 to participate in the state's Medicaid managed care program, Rite Care, established in 1994, and one plan already operating in other states expanded its operations into Rhode Island. Since 1996, another out-of-state HMO has been licensed in Rhode Island. In this report, enrollment of Rhode Island residents in HMOs is estimated and characterized using statewide survey data for 1990 and 1996.

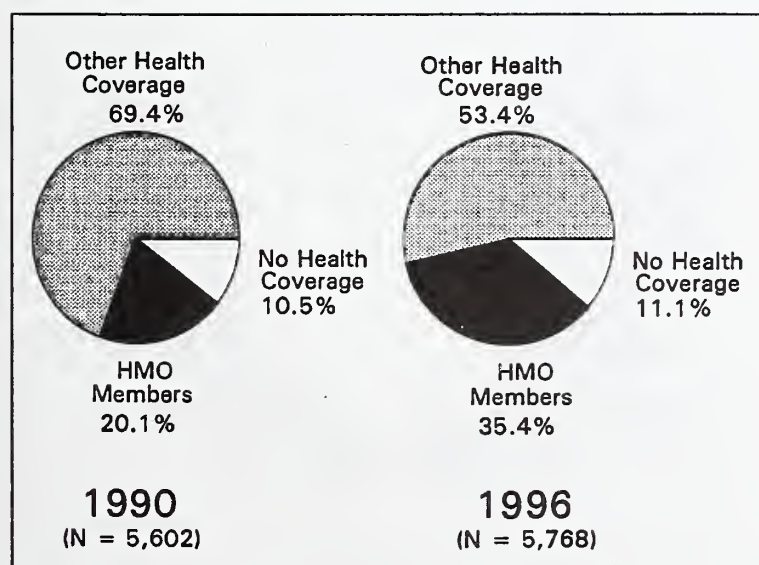


Figure 1. Type of Health Care Coverage, Rhode Island Residents Under Age 65, 1990 and 1996.

Methods

In both 1990 and 1996, the Rhode Island Health Interview Survey, performed by telephone, obtained information on all members of participating households, including demographic, social, and economic characteristics, health status, health-related practices, health care utilization, and coverage for health care costs. In 1990, 6,536 persons were included in the survey; in 1996, 6,583 were included. For each person, the names of any government programs or private health plans providing coverage were obtained. For each private plan, it was further determined whether the plan was provided in whole or part as a benefit of employment, either the covered individual's employment or that of some other household member.

For this analysis, individuals were defined as being HMO members if they were covered by one or more of the state's licensed HMOs (1990: Rhode Island Group Health Association, HMO Rhode Island, and Ocean State Physicians Health Plan; 1996: Harvard Community Health Plan of New England, HMO Rhode Island, United Health Care of New England, Pilgrim Health Care, and Neighborhood Health Plan of Rhode Island) or covered by an HMO operating only out-of-state. Persons not in any HMO were divided into those having coverage from other health plans and those having no coverage. Because of the small number of Medicare enrollees in managed care in 1996 in RI,

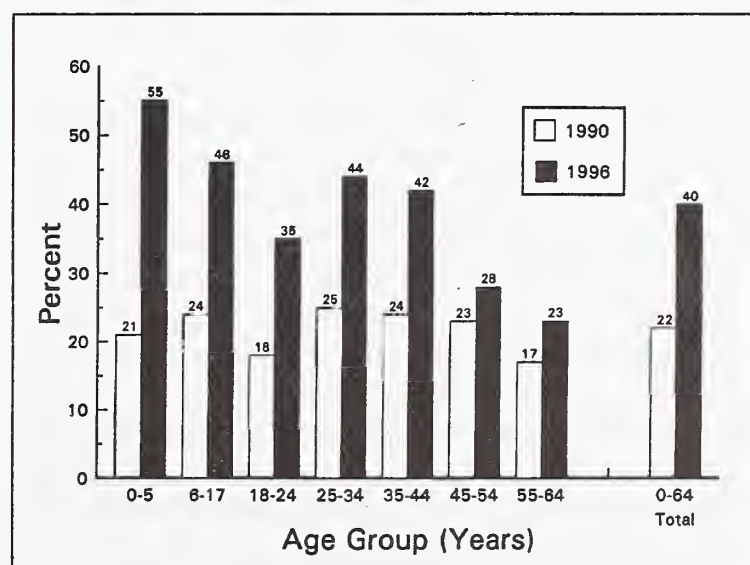


Figure 2. Percentage of Persons with Health Care Coverage Who Are HMO Members, by Age Group, Rhode Island Residents Under Age 65, 1990 and 1996.

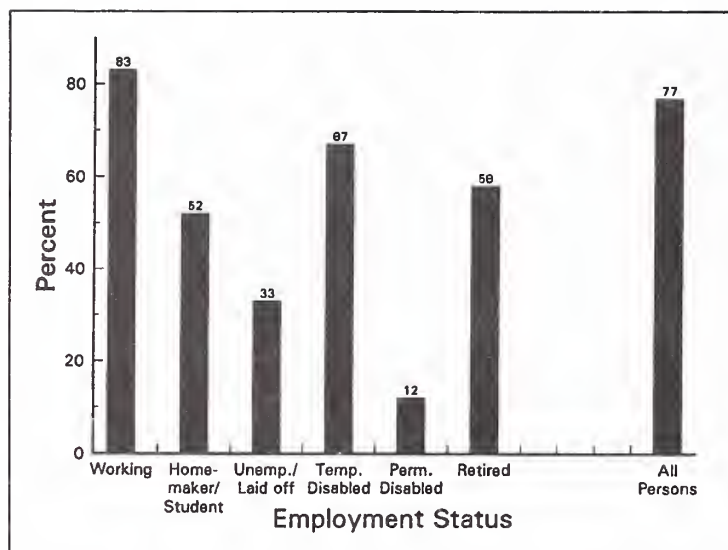


Figure 3. Percentage of HMO Members Whose Coverage is Provided as a Benefit of Employment, Rhode Island Residents Ages 18 through 64 Years, 1996.

this analysis excludes persons ages 65 and older.

Results

In 1996, over one third of the Rhode Island population under age 65 were members of one or more HMOs; this comprises approximately 296,000 persons. (See Figure 1) The proportion increased by three-quarters from the 1990 figure of just over 20%. The proportion of persons in this age group without insurance coverage increased slightly from 1990 to 1996, so the growth in HMOs appears to have been accomplished at the expense of the other health plans.

In 1996, the percentage of the insured population who were HMO members, or the "HMO penetration rate," was greatest for children, exceeding 50% among those under age 6, and was nearly as high among those ages 25 to 44. (See Figure 2) HMO penetration was lowest among those ages 45 and over. By contrast, the variation in HMO penetration by age in 1990 was much less than in 1996, ranging from 17% to 25%. From 1990 to 1996, therefore, the greatest growth in HMO enrollment has been among those under age 18, followed by persons ages 18 to 44 years. There was relatively little growth in HMO enrollment among persons ages 45 and over.

Among HMO members ages 18 through 64 years, the large majority received their coverage through their employer or through the employment of another member of their household. (See Figure 3) The proportion receiving employer-paid coverage varied substantially according to the individual's employment status. The proportion was highest for those who were employed full-time or part-time, and also high for homemakers and students, for temporarily disabled persons, and for retired persons. The proportion was very low for the permanently disabled, who are eligible for Medicare coverage, and low also for persons who were unemployed or laid off.

Discussion

Between 1990 and 1996, HMO enrollment among Rhode Island residents under age 65 grew by an estimated 124,100 persons, most of this expansion occurring among children and younger adults. The increase reflects in part the enrollment of over 70,000 people, primarily women of child-bearing age and their children, in private HMOs under RItE Care, Rhode Island's Medicaid managed care program, which was established in 1994.

For most members of HMOs, coverage was obtained as an employee benefit, and for many others, coverage was obtained through a government program. This pattern among HMO members is consistent with recent moves by private-sector businesses and by state governments in Rhode Island and elsewhere to encourage enrollment in managed health care plans for cost-containment and other purposes. In Rhode Island, the striking change in enrollment patterns over the six-year period examined shows how effective this effort has been.

Reference

1. National Center for Health Statistics. *Health United States and Injury Factbook, 1996-97*. Hyattsville, MD: Public Health Service. (July 1997)

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The Diagnosis and Management of Osteoporosis: Current Considerations

John P. Fulton, PhD

In late 1997 The European Foundation for Osteoporosis and Bone Disease published a position paper in *Osteoporosis International* entitled "Guidelines for Diagnosis and Management of Osteoporosis."¹

The guidelines were written for primary care providers, recognizing that "the increasing availability of diagnostic tools and well-proven treatments, and the increasing numbers of patients identified, indicate that the burden of management will fall increasingly on the primary care physician." The following is a synopsis of major points.

DEFINITION

"Osteoporosis is a progressive systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue."

DIAGNOSIS OF OSTEOPOROSIS

Of the two phenomena which define osteoporosis, low bone mass and microarchitectural deterioration of bone tissue, the former may be measured more precisely and accurately than the latter, and thus "forms the basis for the diagnosis of osteoporosis."

Bone mass is usually measured by scanning the wrist, spine, or hip. The wrist may be scanned accurately with single-energy x-ray absorptiometry (SXA). The spine or hip may be scanned accurately with dual-energy absorptiometry using either photons (DPA) or x-rays (DXA). SXA, DPA, and DXA yield measurements of bone mineral density (BMD), which are measured against the normal distribution of BMD in a young healthy population, using T-scores. T-scores between -1 and -2.5 (between 1 and 2.5 standard deviations below the mean BMD for young, healthy adults) denote osteopenia (significant risk of developing osteoporosis in the future). T-scores ≤ -2.5 (2.5 or more standard deviations below the mean BMD for young, healthy adults) denote osteoporosis (significant risk of sustaining fractures). T-scores ≤ -2.5 (2.5 or more standard deviations below the mean BMD for young, healthy adults) in the presence of one or more documented fragility fractures denote established osteoporosis (significant risk of sustaining fractures). These thresholds were es-

tablished for white women, but are used for other populations. Attributing fracture risk based on BMD is similar to attributing stroke risk based on blood pressure. There are no absolute thresholds above or below which the risk of fracture is either 0% or 100%.

Bone scans may be taken at individual sites (wrist, spine, or hip) or multiple sites. Scanning more than one site yields only a small advantage, because osteoporosis is a systemic disease. However, the correlations among BMDs in the wrist, spine, and hip are not perfect. For this reason, to estimate the risk of fracture most accurately at a particular site, that site should be scanned. The hip may be chosen for elderly patients, for example, because the morbidity and mortality associated with hip fracture are significant in this population. The spine may not be an appropriate single site of measurement in elderly patients, because the measurement of BMD is affected by osteoarthritis, osteoarthritis, and lumbar fractures.

In addition to SXA, DPA, and DXA, other techniques to measure BMD include quantitated computed tomography, ultrasound, and radiographic density measurements of bones in the hand, but they have not been adopted for widespread use thus far.

IDENTIFICATION OF PATIENTS WITH OSTEOPOROSIS

No consensus has been reached on the mass screening of asymptomatic individuals. BMD is measured in those individuals "who have strong risk factors to optimize selection for treatment, provided that it will influence management decisions for the patient." Risk factors which indicate bone densitometry include: estrogen deficiency (premature menopause {<45 years}; prolonged secondary amenorrhoea {>1 year}; primary hypogonadism); corticosteroid therapy (>7.5 mg/day for 1 year or more); maternal family history of hip fracture; low body mass index (<19 kg/m²); other disorders associated with osteoporosis (anorexia nervosa; malabsorption; primary hyperparathyroidism; post-transplantation; chronic renal failure; hyperthyroidism; prolonged immobilization; Cushing's syndrome); radiographic evidence of osteopenia and/or vertebral deformity; previous fragility fracture, particularly of the hip, spine, or wrist; loss of height;

Diagnostic Category	Risk of Fracture	Action
Normal	Low	No intervention
Osteopenia	Medium	Consider prevention in perimenopausal women or assess bone loss. Consider treatment in more elderly with history of fragility fractures.
Osteoporosis	High	Exclude contributing causes, particularly if young. Intervention recommended particularly if less than 75 years of age.
Established Osteoporosis	Very high	Exclude contributing causes. Intervention strongly indicated

From *The Sheffield Protocol for the Management of the Menopause Under the Prevention and Treatment of Osteoporosis*. 4th edition. Osteoporosis 2000, PO Box 2000, Rotherham, S61 2YU, UK.

thoracic kyphosis.

Measurement of BMD in individuals with strong risk factors is preferred to blind treatment, "because not all patients with strong risk factors will have osteoporosis." There are exceptions, however. On the one hand, measurement of BMD may be indicated in the absence of strong risk factors, for example, to inform a decision to use hormone replacement therapy or an alternative therapy to prevent osteoporosis in perimenopausal, menopausal, or postmenopausal women. On the other hand, treatment may be indicated without measurement of BMD, for example, in patients with fragility fractures.

INVESTIGATION OF PATIENTS WITH OSTEOPOROSIS

Five aims are suggested for the investigation of patients with osteoporosis: "1) To exclude a disease that can mimic osteoporosis; 2) To elucidate causes of osteoporosis and contributory factors; 3) To assess the severity of osteoporosis in order to determine the prognosis of the disease, i.e., the risk of subsequent fractures; 4) To select the most appropriate form of treatment; 5) To perform baseline measurements for subsequent monitoring of treatment." The diagnostic procedures to be employed include:

Routine: "History and physical examination; blood cell count, sedimentation rate, serum calcium, albumin, phosphate, alkaline phosphatase, liver transaminases, serum protein electrophoresis, urinalysis; radiograph of lumbar and thoracic spinal column; bone mass measurements (DXA

or SXA); testosterone and gonadotrophins (in men)"

Optional: "Serum and urine markers of bone turnover; serum PTH, 25-OHD, TSH, cancer markers; gonadotrophins; urinary free cortisol; bone marrow examination; iliac crest bone biopsy after tetra-

cycline double labelling for histomorphometry and marrow analysis"

A differential diagnosis must consider osteomalacia, malignancy, and other disorders:

Osteomalacia: "Osteomalacia is characterized by a defect of mineralization of bone matrix most commonly due to impaired intake, production or metabolism of vitamin D. Other causes include impaired phosphate transport or the chronic use of some drugs such as aluminum salts (and other phosphate-binding antacids), high doses of fluoride or etidronate, and chronic use of antacids and anticonvulsants. In most cases the diagnosis of osteomalacia is suspected by the clinical history and by abnormalities in biochemical tests such as low values of serum and urinary calcium, serum phosphatase and 25-hydroxyvitamin D, and high values for alkaline phosphatase and parathyroid hormone. A transiliac bone biopsy after tetracycline labelling may be necessary to demonstrate a defect in mineralization unequivocally."

Malignancy: "Diffuse osteoporosis with or without pathological fracture is common in patients with multiple myeloma, a condition suspected by the severity of bone pain, increased sedimentation rate and Bence Jones proteinuria and identified by marrow aspirate, serum and urine (immuno)electrophoresis of proteins. Similarly, pathological fractures due to metastatic malignancies can mimic osteoporosis and can be excluded by clinical and radiological examination, biological tests and scintigraphy or other imaging techniques."

Other Disorders: "Vertebral fractures in osteoporosis should be differentiated from vertebral deformities due to other disorders such as scoliosis, osteoarthritis and Scheurmann's disease."

DECISION TO TREAT

After a diagnosis, the following actions are recommended: (See table.)

When considering treatment for elderly patients, especially those over age 75, life expectancy and the presence of other factors which may contribute to fracture, such as the



risk of falling, should be analyzed.

NON-DRUG TREATMENT OF OSTEOPOROSIS

Mobility: Patients should be counseled to get regular daily exercise. Moderate, weight-bearing exercise such as walking is good. Vigorous exercise does not add much benefit. Very vigorous exercise may actually contribute to bone loss through gonadal insufficiency.

Nutrition: Patients should consume 400 IU of vitamin D daily. Elderly patients may require as much as 800 IU of vitamin D daily. More than this amount increases the risk of toxicity. The risk of vitamin D deficiency increases with decreasing exposure of the skin to sunlight. Therefore, the risk is high among institutionalized patients, whose exposure to sunlight is minimal, and in winter among all patients who reside in latitudes where the intensity of sunlight is insufficient for the skin to manufacture vitamin D. [Rhode Island is included in the latter.]

Although the level of calcium required by children, teens, and young adults to achieve peak bone mass is controversial, "there is little disagreement that an adequate intake of calcium attenuates, though does not reverse, bone losses in individuals with osteoporosis." Irrespective of diagnosis, the National Osteoporosis Foundation recommends 1000 mg/day of elemental calcium for all men over 24 years of age, 1000 mg/day for women from 24 years of age to menopause (1200 mg/day if pregnant or breastfeeding), 1000 mg/day for postmenopausal women on estrogen, and 1500 mg/day for postmenopausal women not on estrogen.²

Treatment of Associated Disorders and Reduction of Risk Factors: The treatment of diseases associated with osteoporosis "may prevent the progression of the disorder." The reduction of risk factors such as smoking, excessive alcohol consumption, and drug therapy which increases the risk of falls (hypnotics, psychotropic drugs, overtreatment with medications for hypertension) is also beneficial.

DRUG TREATMENT OF OSTEOPOROSIS

Hormone Replacement Therapy: "In women with postmenopausal osteoporosis, hormone replacement therapy (HRT) should be considered early in a management program." HRT retards bone loss, "irrespective of the age of the individual, and the effects persist for the duration of treatment." Patients should be counselled thoroughly on the benefits and risks of HRT.

Calcium: "The doses of calcium required to attenuate bone loss are pharmacological, and the diet should be supplemented with an additional 1000-1500 mg daily." Daily doses should be divided "so that each dose does not exceed 500 mg, since the additional gains from larger doses are trivial." [Assure adequate intake of vitamin D with the calcium.]

Calcitonin: Calcitonin, available in a nasal spray, inhibits bone resorption, has analgesic effects, and has no absolute contraindications other than allergy (rare). "It is

an attractive option for the acute management of vertebral fracture."

Biphosphonates: Biphosphonates also inhibit bone resorption. Oral alendronate is commonly prescribed in the U.S. It may cause upper intestinal and esophageal irritation in some patients, but has clearly demonstrated benefits on BMD and the incidence of fractures.

MONITORING OF TREATMENT

General Measures: Weight, height, clinical risk factors, recent drug intervention, and peripheral fractures should be assessed at regular intervals appropriate to the severity of illness. Lateral radiographs of the thoracic and lumbar spine are indicated to assess possible vertebral fractures if the patient complains of acute back pain or has lost more than 1 cm of height.

Repeated Bone Mass Measurement: DXA or SXA may be repeated at intervals to monitor BMD. Given the rate at which changes in BMD are likely to take place, and given the precision of DXA and SXA, repeating BMD more frequently than every two years "may not be helpful for the physician's decision making about treatment efficacy."

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Offprint requests: J. Kanis, WHO Collaborating Centre for Metabolic Bone Diseases, Department of Human Metabolism & Clinical Biochemistry, University of Sheffield Medical School, Beech Hill Road, Sheffield S10 2RX, UK. Tel: +44 (0)114 271 2649. Fax: +44 (0)114 273 9176.
2. Lindsay RH. *Osteoporosis: A General Guide to Diagnosis and Treatment*. NY: Raven Press, 1992.

*1 CME CREDIT INTERNET COURSE

Dr. Robert Levin of Boston University Medical School has written an internet course on the prevention, diagnosis, and treatment of osteoporosis. Access to the course is free, but \$4.00 is assessed if the user wishes to obtain a certificate for one CME credit upon passing an online test. <http://med/www.bu.edu/cme/online.html>

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Judicial Diagnosis

Physician Unions: The Wave of the Future?

Michele B. Lederberg, JD, MPH

Physician attempts to unionize have become increasingly common, in part because many physicians feel that under managed care they have lost control over fees as well as patient care decisions. For some physicians, the collective bargaining unit of a union may allow them to level the playing field when negotiating with managed care companies, especially when negotiating fees and control over patient care.

Not all physician attempts to unionize have succeeded. Legal limits exist on physicians' ability to unionize. Under labor laws, physicians can only unionize for purposes of collective bargaining if they are employees. Thus, physicians in private practice cannot legally participate in a collective bargaining unit of a union unless they can prove that they act in the capacity of employees. Physicians who are not employees, but who function as independent contractors and who attempt to negotiate collectively on fees, risk violating the antitrust laws.

Consequently, when competitors agree collectively on prices, that collaboration constitutes price fixing, which is illegal. When faced with a challenge to such an agreement, a court or a governmental regulator will not review the agreement to determine its rationale or possible benefits, but instead will find that the participating parties have automatically violated the antitrust laws. Both the Federal Trade Commission and the Department of Justice have made clear that they will monitor agreements among competing physicians to ensure that they do not violate those laws.

Even if a physician acts as an employee, s/he still may not be eligible to participate in the collective bargaining unit of a union. Under the National Labor Relations Act (NLRB), which requires employers to recognize and negotiate with an authorized collective bargaining unit of a union, no employer is required to bargain with supervisors. Traditionally, physicians have been considered supervisors because in providing patient care they normally provide direction to a team, including nurses, physician assistants, and others. However, more recently it appears that the NLRB has not generally challenged a union's assertion that most physician employees do not act as supervisors.

In spite of the limitations, according to the American Medical Association approximately 3% of practicing physicians currently participate in unions. That number will likely increase. However, the rate at which physicians union-

Abbreviations Used:

NLRB National Labor Relations Board

ize will largely depend on whether physician groups can convince the NLRB that the term "employee" includes physicians other than those who traditionally receive a single paycheck and benefits from one employer who directs that person's actions.

In the most recent NLRB action concerning physician unions, the NLRB rejected a petition by a group of 300 New Jersey physicians to join the United Food and Commercial Workers Local 56. On January 8th of this year, the Regional Director of the NLRB in Philadelphia denied the physicians the opportunity for a hearing because she found that the physicians acted in the capacity as independent professionals, not as employees. In this case, the physicians claimed they acted as employees of an HMO (AmeriHealth), with which they participated. Although the physicians were not employees of the HMO in the traditional sense, the physicians claimed that they acted in the capacity of employees because the requirements imposed by the HMO on its participating physicians resulted in a loss of their ability to exercise independence over their practices. The physicians asserted that AmeriHealth dictates how much time they spend with patients, their hours of coverage, provisions for coverage during non-business hours, and the amount of insurance each physician must carry.

Although the NLRB Regional Director recognized that certain rules imposed by AmeriHealth could indicate employee status, the Regional Director decided that the physicians did not act as employees. In her letter to the union, the Regional Director noted that in addition to participating with AmeriHealth, all of the physicians participate with other health plans and have both private paying and Medicare patients. Furthermore, the physicians maintain the identity of their own practices, do business in their own names and hire their own staffs. Most significantly, the physicians retain the ability to make the fundamental decisions which determine the profitability of their practices, thereby retaining the right to decide whether they will remain sole practitioners or enter into a group practice and whether they will become affiliated with any or several HMOs.

The NLRB Regional Director did acknowledge that in order to participate with AmeriHealth physicians must become credentialed in accordance with a process designed by AmeriHealth. Once physicians are credentialed they must comply with the Provider Service Agreement which sets forth the rules and conditions of participation with AmeriHealth as well as the reimbursement arrangements. Although these factors could mark employee status, the Regional Director found that, in the present case, the New Jersey HMO Act and related administrative regulations mandate many of the procedural and credentialing requirements imposed by AmeriHealth upon its participating physicians.

The Regional Director also found other factors that could support a finding of employee status. In particular, the inability of physicians to negotiate with AmeriHealth as to the terms of the Agreements supported such a finding. Furthermore, because the agreement between AmeriHealth and its participating physicians continues indefinitely absent a decision by either party to terminate, the relationship suggests an employee/employer. Nevertheless, the Regional Director found that the physicians acted as independent contractors.

The battle in this case continues: the union has indicated that it will appeal the Regional Director's decision to the NLRB's main office in Washington. Meanwhile, another New Jersey physician group is campaigning to join Local 15 of the International Association of Machinists and Aerospace workers. These physicians also contract with several HMOs and maintain their separate identity. However, they do not believe their campaign for recognition of a union is affected by the recent NLRB decision.

In Rhode Island, the level of physician unionization remains low, probably because very few physicians are employees in the traditional sense. Most physicians still practice independently and therefore cannot collectively bargain with health plans on price without risking a violation of the antitrust laws. These physicians can only participate in the collective bargaining unit of a union if a group can prove to the NLRB that they acted as employees of a health plan because of the manner in which they are re-

quired to deal with the health plan. Based upon the recent NLRB decision in New Jersey, the success of such a request is uncertain. First, the majority of physicians participating with a health plan must support the idea of forming a union. Even with widespread support, the NLRB would likely find that Rhode Island physicians do not act as employees of the health plans with which they participate. Such a finding could be supported by a review of the recently enacted Health Care Accessibility and Quality Assurance Act (known as the Zainyeh Bill), which along with other Rhode Island laws and regulations, dictates the manner in which health plans deal with physicians. Furthermore, the Rhode Island Department of Health also closely regulates such relationships.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	September 1997	12 Months Ending with September 1997	
	Number	Number	Rates
Live Births	1,206	13,286	13.4*
Deaths	708	10,008	10.1*
Infant Deaths	(6)	(92)	6.9#
Neonatal deaths	(5)	(77)	5.8#
Marriages	914	8,183	8.3*
Divorces	255	3,103	3.1*
Induced Terminations	413	5,572	419.4#
Spontaneous Fetal Deaths	97	1,014	76.3#
Under 20 weeks gestation	(90)	(933)	70.2#
20+ weeks gestation	(7)	(81)	6.1#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	March 1997	12 Months Ending with March 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	292	3,408	344.2	4,953.0
Malignant Neoplasms	202	2,508	253.3	6,967.5
Cerebrovascular Diseases	52	623	62.9	1,036.5
Injuries (Accident/Suicide/Homicide)	22	350	35.3	6,300.5
COPD	40	458	46.3	260.0

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

DAVID N. NEWHALL, MD

Dr. David Nason Newhall of Sutton died December 8, 1996.

Born in Salem, Mass, he grew up in Marblehead, Mass., and had lived in Rhode Island for many years before moving to Sutton six years ago.

He was a graduate of Phillips Exeter Academy, Harvard College and Tufts Medical School. He completed his post-graduate medical training at Rhode Island Hospital and practiced internal medicine in East Providence for 22 years.

Dr. Newhall was a fellow of the American College of Physicians and member of the American Medical Association, American Society of Internal medicine, Rhode Island Medical Society and New Hampshire Medical Society.

Dr. Newhall leaves his wife, Virginia Newhall, of Sutton; two daughters, Ann Walters of Lake Bluff, Ill., and Virginia Rademacher of Lynchburg, Va; five grandchildren; two brothers, John Newhall of Manchester, Mass., and Stephan Newhall of Plainfield, Vt.

CHARLES P. EARLEY, MD

Dr. Charles P. Earley of Coventry died February 1, 1997. He was the husband of the late Kathleen M. (O'Brien) Earley.

Born in Worcester, he lived in Providence and Cranston before moving to Coventry 35 years ago. When Dr. Earley relinquished his practice in 1996, the Department of Health acknowledged him as "The Dean" of licensed physicians in Rhode Island.

Dr. Earley received his medical degree in 1932 from the Boston University School of Medicine, and did his internship and residency in various Boston hospitals. In 1933 he began his general practice on Prairie Avenue in Providence. He was a staff member at St. Joseph and Kent County Memorial Hospitals. In the 1960s he moved his practice to Coventry.

Dr. Earley was a member of the Rhode Island Medical Society and the American Medical Association. An avid ham radio operator, he assisted in the photographic departments of various hospitals.

He leaves two sons, Charles F. Earley of Shelby, N.C., and Francis P. Earley of Coventry; five daughters, Eileen J. Labbadia of West Simsbury, Conn., Cathleen M. Naughton of Seekonk, Mass., Patricia A. Reilly of Warwick, and Charlene Dalton and Deborah M. Fontes, both of Coventry; 21 grandchildren and 7 great-grandchildren. He was a brother of the late Ellen Lovett and Anne DuVally.

DONALD S. LEE, MD

Dr. Donald S. Lee of Cranston died February 24, 1997. He was the husband of In O. (Han) Lee. Born in Ham-Heung, Korea, he came to this country in 1973, moving to Cranston 17 years ago.

Dr. Lee earned his doctor of medicine degree from Kyung Pook National Medical School and the University of Korea. In 1973 he interned at Atlantic City Hospital, affiliated with Hahnemann Medical Center. In 1977, he received his U.S. medical degree, specializing in pediatrics, and he served as a resident at Columbia-Presbyterian Medical Center. He practiced in New York as a board-certified pediatrician. He served as a house physician at St. Joseph Hospital, and for the last 12 years, had a private practice at Midland Medical Center in Warwick. He simultaneously tended to patients at Rhode Island Hospital and Women & Infants Hospital.

Besides his wife and parents, he leaves two daughters, Susan Lee of New York City and Alice Lee of Boston; three brothers, Dong H. Lee and Dong J. Lee, both in Korea, and Dong M. Lee in California; and a sister, Dong H. Lee in Korea.

DONALD K. O'HANIAN, MD

Dr. Donald K. O'Hanian of Warwick died March 13, 1997. He was the husband of Willene W. (Hunter) O'Hanian. Born in East Providence, he practiced internal medicine in Warwick from 1953 until 1988.

Dr. O'Hanian was a 1943 graduate of Brown University and a 1946 graduate of Georgetown University Medical School.

Dr. O'Hanian was a member of the Rhode Island Medical Society. He was on the staffs of Kent County Memorial Hospital, Memorial Hospital of Rhode Island, and Rhode Island Hospital. He served in the Navy from 1945-1953 and was stationed in London, England, Bethesda, MD, and Newport.

Besides his wife and mother, he leaves a daughter, Anne Szostak of Providence; three sons, Donald K. O'Hanian, Jr., of Warwick, Hunter O'Hanian of Provincetown, Mass., and Mark L. O'Hanian of North Attleboro, Mass., a sister, Marion LeBlanc of East Providence; and four granddaughters. He was the brother of the late Oscar K. O'Hanian, Jr. and Margaret DeMatteis.

JOSE M. RAYOS, MD

Dr. Jose M. Rayos of Woonsocket died March 21, 1997. He was the husband of Patricia (Billetdoux) Rayos. Born in Talisay, the Philippines, he lived in Woonsocket since 1964.

Dr. Rayos was a 1953 graduate of the Medical School at Manila Central University, and was an intern at Glens Falls Hospital in Glens Falls, N.Y. He was a Fellow of the American Family Physicians, and a member of the American Medical Association and the Rhode Island Medical Society. Dr. Rayos was also a member and past treasurer of the Woonsocket Medical Society.

Besides his wife, he leaves four sons, Leon Rayos of Woonsocket, Jose Rayos of Blackstone, Mass., Juan Rayos of Charlotte, N.C., and Patrick Rayos of Mendon, Mass.; three daughters, Josephine Beauchamp and Mary Stone, both of Blackstone, and Paulette Adams of Holliston, Mass.; two brothers, Domingo Rayos of Markina, the Philippines and Emanuel Rayos of Talisay; three sisters, Eya Jamito and Juanita Rayos, both of Talisay, and Soledad Sangcap of Walnut, Calif.; and 15 grandchildren.

ELMER THOMAS GALE, MD

Dr. Elmer Thomas Gale of Narragansett died April 19, 1997. Dr. Gale was a specialist in geriatric medicine and a school physician for the Narragansett School Department before retiring.

Born in Sampson County, N.C., he moved to Narragansett 50 years ago. Dr. Gale earned a medical degree from Duke University Medical School in 1942, and was the university's youngest graduate. He was an Army veteran of World War II, serving as a captain. He was one of the first doctors to write about vitamin C for *JAMA*.

Dr. Gale was a 50 year member of the Rhode Island Medical Society, and a member of the American Medical Association. He was a long-time member of Hope Lodge 25, AF&AM, Wakefield. He leaves a sister, Dorothy G. Philips of Clinton, N.C., and nieces and nephews.

HAROLD A. WOODCOME, SR., MD

Dr. Harold A. Woodcome, Sr., of Reservoir Avenue died May 1, 1997. Dr. Woodcome was the husband of Elizabeth "Sherry" (Sheridan) Woodcome.

Born in Cambridge, Mass., he lived in Rumford for 48 years. Dr. Woodcome was a graduate of Brown University, Class of 1938. He earned his medical degree from Tufts University, Boston, in 1942.

Dr. Woodcome served on the staff of Memorial Hospital of Rhode Island for more than 53 years. He was also on the staff of Notre Dame Hospital, Central Falls. Dr. Woodcome was a captain in the Army's medical corps during World War II and was a recipient of the Bronze Star.

He was past president of the Pawtucket Medical Society and a member of the Rhode Island Medical Society. He was a fellow of the American Academy of Family Practice. Dr. Woodcome was also a member of the Pawtucket Country Club, and a communicant of St. Mary Church,

Seekonk, Mass., and St. Margaret Church, Rumford.

Besides his wife, he leaves two sons, Dr. Harold A. Woodcome, Jr. of Providence and Dr. H. Ted Woodcome of Pittsford, N.Y.; a daughter, Dr. Elizabeth "Betty" Howard of Farmington, N.Y.; a sister, Doris Murray of Seekonk, and seven grandchildren.

PAVEL VANCURA, MD

Dr. Pavel Vancura of Providence died July 12 1997. He was the husband of Susan (Bump) Vancura. Born in Prague, Czech Republic, Dr. Vancura came to the United States in 1969 to do post doctoral research at Massachusetts General Hospital.

Dr. Vancura earned a doctorate at Charles University in Prague.

He was a partner at Medical and Renal Associates in Warwick and was affiliated with Kent County Hospital in Warwick and Miriam Hospital in Providence. Dr. Vancura's grandfather was president of Charles University and his father was Dean of the Medical School there. Besides his wife, he leaves a son, Peter Vancura of Providence; a daughter, Lucia Vancura of Taiwan; and a brother, Antonin Vancura of Kaiserslautern, Germany.

LOUIS C. CERRITO, MD

Dr. Louis C. Cerrito of Sarasota, Florida, died July 16, 1997. Born in Providence, he had lived in Westerly and had a home in Sarasota since 1947, moving there permanently in 1980.

Dr. Cerrito graduated from the Long Island College of Medicine in 1932 and interned at the Lutheran Medical College, Brooklyn, N.Y. He pursued graduate study at the University of Buffalo; Tufts Medical School; Harvard Medical School; Cook County Hospital, Chicago; and the Boston Dispensary.

Dr. Cerrito was attending surgeon at the Westerly Hospital from 1933 until his retirement in 1980. Dr. Cerrito was a member of the Washington County Medical Society; the Rhode Island Medical Society; the American Medical Association; the American Society of Colon and Rectal Surgeons; and the Northeast Society of Gastroenterology.

Dr. Cerrito was the husband of the late Ruth Hale Cerrito. He married Mary Balmer Smith in 1981. In addition to his wife, he is survived by a son, Charles W. Cerrito of Sarasota; and Marlene Cerrito Hewitt of Potomac, Maryland; and three grandchildren.

THOMAS S. MICOLONGHI, MD

Dr. Thomas S. Micolonghi of Cranston died July 23, 1997. He was the husband of the late Mirdza Klints-Micolonghi, MD.

Born in Lowell, Mass., he had lived in Smithfield since 1963. Dr. Micolonghi retired in 1993 from Memorial Hospital. He was a graduate of the medical school at the University of Rome, and interned at the Polyclinic Hospital, Clinic of Tropical and Subtropical Disease in Rome from 1949-51. He was an intern at St. John Hospital in Lowell,

Mass., from 1951-52.

Dr. Micolonghi was acting pathologist-in-chief at Memorial for nine years, until 1980, and pathologist-in-chief until 1987. He was pathologist-director at South County Hospital for 15 years. Dr. Micolonghi had been a teaching fellow at Tufts University Medical School, 1954-55; an assistant in pathology, 1955-56; an instructor in pathology, 1956-57; and a senior instructor in pathology, 1967-71.

Dr. Micolonghi was the director of the Memorial Hospital School of Medical Technology from 1972-73, and was chairman of the board of Rhode Island Schools of Medical Technology from 1977-78. Dr. Micolonghi was a clinical instructor in pathology, a clinical assistant professor in pathology and a clinical associate professor of pathology at the Brown University School of Medicine.

He had served as chairman of the transfusion review committee at Memorial, medical director of the blood bank and transfusion service, president of the Rhode Island Society of Pathologists, and president of the Rhode Island Association of Blood Banks.

He leaves two daughters, Ede Micolonghi Votta of Scituate and Emily C. Micolonghi of Boston; a sister, Rita Micholonghi Calvari, and a brother, Americo Micholonghi both of Rome; and a granddaughter.

ROBERT W. DREW, MD

Dr. Robert W. Drew of Barrington, a founder in 1963 of the Bristol County Medical Center, died September 10, 1997. He was the husband of Frances (Weaver) Lathrop Drew and of the late Thea (Melchior) Drew.

Born in Montclair, N.J., he lived in Barrington for 50 years. Dr. Drew was a 1932 graduate of Wesleyan University and received his medical degree from Harvard Medical School in 1936. He trained at Rhode Island Hospital and the former Chapin and Lying-In Hospitals. In 1940 he opened his office as a general practitioner in Warren. He was a captain in the Army Medical Corps during World War II.

Governor John H. Chafee appointed him to the Health Facilities Planning Council, and the successor Health Services Council in 1960. Re-appointed by Governor Frank Licht, Dr. Drew served until 1978. He was a volunteer with several community groups, including the Barrington YMCA, which he served as president, the Samaritans, the Nayatt Elementary School Kindergarten Grandparent Program, Barrington Conservation Commission, Barrington Land Trust. Audubon Society of Rhode Island, and Luethi-Peterson Camps for International Understanding. He volunteered his medical services internationally on the hospital ship Hope in 1973, with Care Medico in Java in 1976, and with International Center of Diarrheal Research in Bangladesh in 1984.

Besides his wife, he leaves two sons, Thomas M. Drew, MD, of Providence, and Walter M. Drew of Santa Fe, N.M.; three daughters, Helen Drew of Providence, Deborah Drew, CNM, of Peace Dale, and Lois Drew of Portland, Ore.; 26 grandchildren and 3 great-grandchildren.

BENJAMIN S. MCKENDALL, MD

Dr. Benjamin S. McKendall of Longwood, Florida, formerly of Providence and Pawtucket, died October 3, 1997. He was the husband of the late Pauline McKendall.

Born in Providence, Dr. McKendall had lived in Pawtucket since 1940 and moved to central Florida in 1991. Dr. McKendall was a member of the Rhode Island Medical Society and the American Medical Association. He was a graduate of Brown University. He was a 1930 graduate of Harvard Medical School and a member of its Alumni Association.

Dr. McKendall leaves two sons, Benjamin McKendall, Jr. of Longwood and Robert McKendall of Dickenson, Texas; a daughter, Audrey McKendall of New York City; two sisters, Vera McKendall and Eva McKendall, both of Providence; and five grandchildren. He was a brother of the late William E., Albert N. and H. Raymond McKendall.

JOHN A. MELCHIONNA, MD

Dr. John A. Melchionna of Cranston died October 8, 1997. He was the husband of Pia (Carpentieri) Melchionna.

Born in Carife, Italy, he lived in Cranston since 1969. Dr. Melchionna received his medical degree at the University of Pisa as a member of the class of 1958. He was clinical director at the Institute of Mental Health from 1967 to 1990, and a staff psychiatrist at the Veterans Administration Medical Center, Providence, from 1991 to 1995.

Dr. Melchionna was a member of the Rhode Island Medical Society, the American Psychiatric Association and a member of Associazione Marinai Nazionale Italia. He was also a communicant of St. Marks Church in Cranston.

Besides his wife and mother, he leaves a son, Dr. Emilio M. Melchionna of Long Meadow, Mass.; two daughters, Theresa M. Rhein of Mansfield, Mass., and Laura A. Crupi of Ashland, Mass.; one brother, Vito Melchionna of Pisa, Italy; one sister, Lelia Tarantino of Avellino, Italy; and four grandchildren.

JOHN A. FERRIS, MD

Dr. John A. Ferris of Warwick died October 11, 1997. He was the husband of the late Alpha B. (Smith) Ferris. Born in Cranston, he moved to Warwick in 1952.

Dr. Ferris was an Army veteran of World War II and the Korean War, and served as a captain in the Medical Corps. He was a graduate of the University of Rhode Island and a 1945 graduate of Boston University School of Medicine. Dr. Ferris did his residency at Mercy Hospital in Baltimore. He was a former member of the American Medical Association and the Kent County Medical Association. He was a president of the Kent County Medical Science Society. In 1964 he served in Vietnam with Care Medico. He was a volunteer aboard of the medical mercy ship Hope in Tunisia in 1970.

In recognition of his leadership in the natural childbirth movement, a birthing room was named after him at Kent County Memorial Hospital. Also named after him were health centers in Warwick and West Warwick, where

he volunteered after retirement. The Dr. Ferris Community Health Center was dedicated on June 16, 1990 by Warwick Mayor Francis X. Flaherty.

Dr. Ferris leaves a daughter, Judith Ann Ferris of Warwick; and two brothers, William W. Ferris of Warwick, and Richard Ferris of Ft. Myers, Fla.

EDWARD B. MEDOFF, MD

Dr. Edward B. Medoff of Woonsocket died October 28, 1997. He was the husband of Sylvia (Darman) Medoff.

Born in Woonsocket, Dr. Medoff was a member of Congregation B'nai Israel. He was a 1929 graduate of Brown University and a 1933 graduate of Harvard Medical School. Dr. Medoff served as a major in the Army during World War II with the 42nd Infantry Division. He completed his internship and residency at Rhode Island Hospital, the former Lying-In Hospital and the former Charles V. Chapin Hospital.

Dr. Medoff was president of the Woonsocket district Medical Society from 1955 to 1959, and joined the Woonsocket Hospital staff in 1939 as a general internist. He served as a major in the Army Medical Corps with the 122nd Medical Battalion in France, Germany and Austria.

Dr. Medoff was a member of the American Academy and Family Physicians, and the American Medical Association. He served on the staff of the former Fogarty Hospital and at Miriam Hospital. He was past director of the state division of the American Cancer Society, and a member of the American Legion, B'nai Brith and Congregation B'nai Israel. He was president of the Woonsocket Hospital staff in 1966 and 1967.

Besides his wife, he leaves a son, James L. Medoff of Concord, Mass.; a daughter, Joanne D. Medoff in New York and Woonsocket; two sisters, Eve Goldberg and Brenda Smira, both of Providence; and two grandchildren.

SEEBERT J. GOLDOWSKY, MD

Dr. Seebert J. Goldowsky of Providence died November 5, 1997. He was the husband of Bonnie (Nisson) Goldowsky.

A lifelong Providence resident, Dr. Goldowsky was a 1928 graduate of Brown University and a 1932 graduate of Harvard Medical School. During World War II, he served as a combat surgeon in the Army Medical Corps in the Southwest Pacific.

Dr. Goldowsky was an active general surgeon in Providence before becoming the first full-time medical director of Blue Cross/Blue Shield of Rhode Island in 1972.

During his long career he served as chief of the department of surgery at Miriam Hospital and served two terms as president of its staff. He was also on the staffs of Rhode Island Hospital, Charles V. Chapin Hospital and Roger Williams Hospital.

Dr. Goldowsky was a member of numerous scientific and medical organizations and was clinical lecturer in surgery at Brown University School of Medicine. He was editor-in-chief of the Rhode Island Medical Journal for 27 years.

He was the author of *Yankee Surgeon, The Life and Times of Usher Parsons 1788-1868*, and *A Century and a Quarter of Spiritual Leadership: The Story of the Congregation of the Sons of Israel and David*. He wrote more than 60 articles for scientific and historical journals and periodicals.

In 1991, he received the Recognition Award of the Brown University School of Medicine and in 1995 the Williams Award of the Brown University Library, to which he donated a substantial portion of his literary collection. He was elected chairman of the Rhode Island Interagency Council on Smoking in 1976.

Besides his wife, he leaves several nieces and nephews.

BARBARA A. FRITZ, MD

Dr. Barbara A. Fritz of East Providence died December 14, 1997. Born in Newport, she had lived in East Providence since 1972.

Dr. Fritz maintained a ob/gyn practice on North Main Street in Providence, and since 1971, had been an attending physician at Women & Infants Hospital. She was a 1953 graduate of Bennington College and earned her medical degree from Tufts University School of Medicine in 1963.

Dr. Fritz was a member of the American Society for Reproductive Medicine, the Rhode Island Medical Society, the Surgical Committee of Women & Infants Hospital and the Alpha Omega Honor Medical Society. She leaves no immediate survivors.



Philately in Medicine

John Tierney

A Philatelist's History of Smallpox Variolation



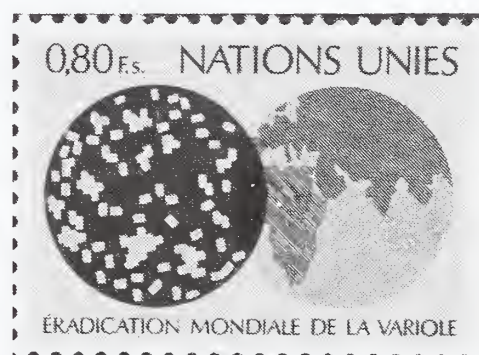
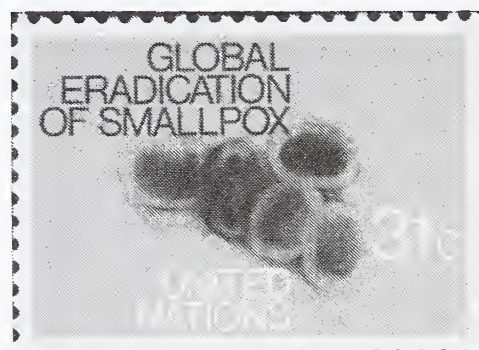
In 1760, Queen Maria Theresa (1717-1780) of Austria decided to have her children variolated against small-

pox. Despite vociferous objections, the Queen was determined to have her two sons protected since she had previously lost the two other sons and eleven other members of her family to the disease over a 50-year period [Austria, 1980, #1150].

The Queen had learned of the knowledge and skill of Dr.

Jan Johannes Ingenhousz (1730-1790, [The Netherlands, 1991, B#135]), a Dutch physician and member of the Royal Society of London. His smallpox control programs were touted as successful; and the Queen invited him to London to provide variolation to the Queen's family.

At the onset, the Queen insisted that Dr. Ingenhousz variolate 200 Austrian children of the community prior to variolating the Royal Family. This was done without any untoward incident.



Over the objections of many, Queen Maria Theresa ordered the variolations for her family, which were accomplished without complications. Her example encouraged other Austrians to protect their families.

Two United Nations stamps also commemorate smallpox vaccination [United Nations 1978, #295; United Nations, Geneva, 1975, #74].

CORRESPONDENCE:

J.T. Tierney
111 Amherst Avenue
Pawtucket, RI 02860



NINETY YEARS AGO

✿ [MARCH, 1908] ✿

Robert B. Greenough, MD, of the Massachusetts General Hospital wrote the lead article on the operative treatment of breast tumors (from a speech presented before the Providence Medical Association). He notes, first, that operative treatment of breast disease has assumed an increasing role in modern surgery. Further, breast cancer is second only to uterine cancer in women and represents a tangible threat to their health and survival. The author decries the morbid fears of cancer which prevent many women from seeking surgical help, often waiting until it is too late to undertake any form of intervention. He concludes that "the vast majority of benign tumors of the breast in women of adult age demand operative removal first because of the uncertainty of the diagnosis, second on account of the possibility of malignant disease developing in them secondarily, and third, as the most rapid and effective method of relief." The article provides the reader with detailed surgical instructions as well as guidelines for operating and when to avoid surgery. The article departs from the great majority of *Journal* articles in that the author cites numerous medical references.

FIFTY YEARS AGO

✿ [MARCH, 1948] ✿

In an issue devoted largely to medical education, the lead article, by James M. Faulkner, MD, describes the precarious position of the general practitioners and speculates on their future. He summarizes the recently stated objectives of the American Academy of General Practice. The first of these goals is to promote and maintain high professional standards. Second, to encourage and assist in providing post-graduate study for general practitioners. Third, to encourage younger physicians to enter general practice. And fourth, to protect their right to use hospital facilities. He describes steps under way, including the development of sanctioned residency training programs, establishment of a section on General Practice in the American Medical Association, as well as ongoing discussions with the American Board of Internal Medicine regarding liberalization of their formal certification requirements.

Reginald Fitz, MD, presents a paper entitled "Leaves Off the Tree," (his invited speech to the Providence Medical Association on the occasion of their centennial celebration). The author talks about the early days of the Association in January, 1848. He discusses some of the more illustrious members and

their encounters with Oliver Wendell Holmes when he was their professor at Harvard Medical School. Fitz also quotes the eminent Rhode Island, Dr. Benjamin Waterhouse, who, in keeping with Quaker precepts, decried the use of smoking tobacco as nasty, destructive, unhealthy and "productive of indolence."

Oliver Pratt, Executive Director of Rhode Island Hospital, discusses graduate medical education and hospital economics. He applauds the growth of internships and residency training programs but wonders how the hospitals, and society in general, will pay for them. The range of possibilities include the intern himself paying the cost as a form of tuition, to the patient and third party sources picking up the bill.

Dwight O'Hara, MD, dean of Tufts School of Medicine, discusses admission policies for the American colleges of medicine. And Charles F. Wilkinson, Jr, MD, explores internship training in the American hospital, emphasizing the obligation of the hospital, the minimum teaching requirements, the responsibilities of the interns and residents and the role of the general practitioner in a tertiary medical care facility.

TWENTY FIVE YEARS AGO

✿ [MARCH, 1973] ✿

The address of Joseph E. Caruolo, MD, outgoing president of the Providence Medical Association and the remarks of Thomas F. Head, MD, incoming president are summarized.

Drs. Subhash Bajaj, Leslie Leduc, Raj Goyal and Theodore Hersh discuss a new blood chemistry procedure measuring the levels of alpha-fetoprotein, particularly in patients with benign and malignant disease of the liver. The authors conclude that the procedure does have some modest quantitative implications but cannot be used as an infallible test for hepatoma.

The nitro blue tetrazolium test, as a diagnostic adjunct to the identification of certain infectious diseases, is discussed by Patricia Farnes, MD, Barbara Barker, PhD, and Edwin N. Forman, MD

Srecko Pogacar, MD, Nedo Nora, MD, and Thomas Kemper, MD, present a case of Rubinstein-Taybi syndrome [broad toes, facial abnormalities and mental retardation], with autopsy findings. Their findings, they note, are consistent with the prior findings of others.

The *Journal* prints a message from the new dean of medicine at Brown announcing the formal onset of clinical clerkships at Rhode Island and Miriam Hospitals. "After 130 years of dormancy Brown University has resumed its role as an educator of physicians."



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COMMENTARIES

The Subspecialty of Maternal-Fetal Medicine



As with most areas of specialization in medicine and surgery, the philosophic roots of Maternal-Fetal Medicine have been those of clinical practice and research. By the mid 1970s, numerous physicians with Board certification in Obstetrics and Gynecology were limiting their practice to "high risk" obstetrics. Most were found in academic environments or in large hospitals supporting the transfer of mothers with intercurrent problems in pregnancy. Their practice was based upon an enlarging body of clinical and animal research data concerning maternal and fetal physiology and pathology and driven by the new technologies of neonatal intensive care and sonographic imaging of the conceptus. The burgeoning knowledge of genetics based upon new biochemical and molecular techniques has also reinforced the clinical role of the perinatologist in providing the necessary integrated environment for prenatal diagnosis. The American Board of Obstetrics and Gynecology (ABOG) approved certification in the subspecialty of Maternal-Fetal Medicine in 1974.

Certification led to formation of the Society of Perinatal Obstetricians in 1977 (now the Society of Maternal-Fetal Medicine). This body has fostered "the promotion and expansion of education in obstetrical perinatology and the exchange of new ideas and research in the field of perinatology." Fellowship training has been developed during the past 23 years to include 3 years of clinical and research training following residency. MFM fellowship programs are found in 77 institutions, including Women and Infants Hospital. At present there are approximately 1700 regular and associate members in

the Society. Virtually all departments of Obstetrics and Gynecology engaged in post-graduate education in obstetrics and gynecology are supported by faculty with fellowship training in MFM.

This issue of *Medicine & Health/Rhode Island* focuses on the intellectual "neighborhood" of Maternal-Fetal Medicine. Jacob Canick, PhD, a biochemist and Director of Prenatal AFP and Endocrine Laboratories at Women and Infants Hospital, and Owen Phillips, MD, a clinical geneticist and Consulting Geneticist at the Prenatal Diagnosis Center, both discuss the role of population-based screening for specified congenital defects and the importance of using a family history to identify fetuses at risk for genetic disease. Their articles demonstrate the tremendous impact that laboratory technology has on reproductive care, changing the expectations and management of antenatal care. Marshall Carpenter, MD, discusses the continued challenge of adapting health care to prevent congenital defects such

as diabetic fetopathy and neural tube defects, two of the more common and highly morbid birth defects. Stephen Carr, MD, the Director of the Prenatal Diagnosis Center, discusses fetal growth retardation, a subject that bridges the spectrum between genetics and prenatal diagnosis and perinatal management. Finally, Jami Star, MD, one of our MFM specialists, and Raymond Powrie, MD, an internist and Education Director of the Division of Obstetric Medicine, describe the impact of chronic medical illnesses, human immunodeficiency viral infection and thromboembolic disease on pregnancy, topics that characterize the broad interface between Maternal-Fetal Medicine and Internal Medicine. We hope that the discussions inform clinical practice.

— Marshall W. Carpenter, MD

Marshall W. Carpenter, MD, is Associate Professor, Department of Obstetrics and Gynecology, Brown University School of Medicine.

A Tale of Danbury Hatters, Detectives and Dartmouth Chemists

Lewis Carroll waited until the seventh chapter of *Alice in Wonderland* to introduce three of his most enchanting characters, all participants in a bizarre tea party. There was the March Hare [called March because that is the month when English rabbits are said to mate, and when doing so they characteristically exhibit erratic behavior.] Then there was the dozing Dormouse [the prefix dor-, is derived from an old Scandinavian word meaning sleepy.] And finally there was the Hatter, sometimes called mad.

Carroll, writing his whimsical prose in the middle years of Victoria's reign, might have chosen any one of many occupations for the third tea drinker; but he selected hat-making knowing that his reading public would readily accept, indeed expect, that someone gainfully engaged in hat manufacture would inevitably behave strangely, tremble readily and fit quite comfortably in the outlandish

tea party that Alice, uninvited, had attended. Beyond the humorous caricature of the mad hatter lay the grim reality of a class of hat workers who regularly developed severe systemic disease, including madness, after chronic exposure to the mercurial solutions employed then in the making of felt hats.

Most 19th century hats were fashioned from felt which had been crafted from animal fur [typically rabbit, muskrat or beaver] or wool. The felt industry, at that time, was concentrated in two sites: the English midlands and New England, particularly around Danbury, Connecticut. The making of fur felt required many complex steps from the cleansing of the fur to the final blocking of the matted felt. Fur felt is nothing more than sheetlike masses of densely interlocked fur fibers, sufficiently adherent so that the felt may not be pulled apart easily. Once the hairs are separated from the hide their capacity to cling to each other is considerably enhanced by bathing them in hot solutions of mercuric nitrate.

The majority of workers exposed to this mercuric solution developed signs of mercury poisoning [mercurialism] within months. The mercuric compounds entered their bodies by two routes: when they breathed in mercury fumes and when the solution splashed upon their hands [mercury is readily absorbed through the skin.] After months of exposure the typical worker experienced a foul, often metallic taste in his mouth and salivated excessively. His teeth then loosened, many eventually falling out. These oral changes were shortly accompanied by fine tremors of the hands and facial muscles. Handwriting became awkward, tremu-



lous and jerky. Incoordination of the limbs and a staggering walk then appeared [the "Danbury Shakes"]. These symptoms emerged more rapidly and with greater intensity in those workers who drank much alcohol. Behavioral changes included intermittent paranoia, irritability and explosive rage.

A person suffering from chronic mercurialism was ultimately without teeth, cachectic, confused, intensely suspicious, tremulous and uncoordinated. By the closing decades of the 19th Century most industries employing mercury compounds had finally recognized the grave perils associated with these substances. Less hazardous substances were substituted and industrial mercurialism then became a rare occurrence.

However, a few occupations persisted in employing mercurial derivatives, and their employees continued to develop the inevitable oral changes, tremors and dementia. For example, there was the police detective assigned the task of finding fingerprints at crime scenes. He dusted suspicious surfaces with a powder compounded of mercury salts admixed with pulverized chalk. And in the process of dusting he inhaled the airborne, mercury-contaminated dust. Most police departments have now eliminated the mercury in their dusting powders.

Many Caribbean cultures view native mercury [quicksilver] as something endowed with unique spiritual powers, a substance capable of protecting households, securing jobs and ensuring the fidelity of lovers. Accordingly, many carry small amounts of mercury around their necks encased in amulets. Others are said to spray it upon the floors of their homes to provide protection, not knowing that elemental mercury is volatile at room temperatures. A group of pediatricians has recently begun a major inquiry into the likelihood that some Bronx schoolchildren from such homes may be burdened by chronic mercurialism. Preliminary screening studies have indicated elevated blood levels of mercury in these children. The study now seeks to determine whether the mercury intoxication correlates with defi-



cient school performances in a manner analogous to the proven relationship between chronic lead poisoning and impaired cognition.

The hazards persist even amongst those most aware of mercury toxicology. On August 14, 1996, a gifted professor of chemistry at Dartmouth College performed some experiments on methylmercury, a compound considered by many to be amongst the deadliest of chemicals. This chemist was suitably dressed for the experiment. She wore protective goggles, gloves and worked with scrupulous care. Yet, inadvertently, some methylmercury fell upon her latex glove. And within days she displayed the dismaying neurological symptoms of mercurial poisoning. She died within a few months.

Bitter experience has taught the world something of the menace posed by mercury; each year, though, brings unexpected, new ways in which mercury may inflict damage. There is little doubt that many industries, particularly those concerned with hats, mirrors and gold jewelry, are no longer as hazardous. But the shadow of mercurial poisoning has not yet been lifted. Mercury-containing industrial wastes have polluted the shellfish beds of Minamata Bay in Japan; and the inappropriate use of mercury-containing fungicides has occasionally contaminated the bread supply of Iraq.

Mercury is still viewed as an amusingly quirky liquid element, probably useful for such things as thermometers. It would be well to be aware of mercury's more capricious, untrustworthy contributions to history.

— Stanley M. Aronson, MD

Molecular Genetics: Impact on Prenatal Diagnosis

Owen P. Philipps, MD

Over the past two decades, technological advances have given physicians the ability to understand and diagnose many genetic diseases. Although genetics plays some role in every branch of medicine, the ability to diagnose genetic disease prenatally has had a particularly dramatic impact on obstetrics. This paper will focus on two areas: first, genetic principles and common genetic diseases, and second, molecular genetic techniques used to diagnose disease.

PRENATAL DIAGNOSIS FOR GENETIC DISEASE

It is the obstetrician's obligation to determine whether a woman is at increased risk for having an offspring with a genetic disease. A detailed family history should be obtained because even rare disorders may be prenatally diagnosed. A woman at risk should be offered genetic counseling and testing. This "case finding" differs from population-based screening for congenital defects during pregnancy.

The accuracy of prenatal testing depends on the disorder and the molecular genetic test available for diagnosis. Only the laboratory performing the test can provide this information. Ideally, as much information as possible should be gathered prior to pregnancy (i.e., obtaining records on affected family members, determining whether the disorder can be diagnosed prenatally, identifying the laboratory most experienced in diagnosing the disorder).

The traditional method for obtaining fetal tissue for study has been second-trimester amniocentesis (i.e., ≥ 14 weeks gestation). Usually amniotic fluid cells are grown in culture, with routine karyotyping performed. The cells are then lysed and DNA is extracted for study. Chorionic villus

sampling (CVS) is applicable to all molecular genetic diseases and has advantages over amniocentesis. First, CVS can be performed as early as 10 weeks. Because molecular diagnostic tests may take 2-3 weeks to complete (after a 10-14 day culture period), retrieving a sample at an earlier gestation alleviates a great deal of stress for the family. Second, it yields a relatively large amount of fetal tissue compared to amniocentesis, thereby potentially speeding the process. Early amniocentesis (< 14 weeks) may not be ideal because of the tendency for slower cell growth in culture and the potentially higher pregnancy loss rates.

THE GENETIC BASIS FOR DISEASE

DNA Structure

Deoxyribonucleic acid, or DNA, the molecular basis for human biological function, serves as the template for the formation of proteins and enzymes necessary for life. DNA is comprised of two intertwining chains of nucleotides; purines [adenine (A) or guanine (G)] and pyrimidines [cytosine (C) or thymine (T)] arranged in an alpha-helix configuration. The two strands of DNA are complementary. For example, if the nucleotide sequence on one strand is -AGACGATT-, the sequence on the opposite strand will be

Abbreviations Used:

ASO	allele-specific probes
CF	cystic fibrosis
CVS	chorionic villus sampling
DNA	deoxyribonucleic acid
FISH	fluorescence in situ hybridization
FMR-1	Fragile X syndrome
IVF	in vitro fertilization
kb	kilobase
PCR	polymerase chain reaction
PRINS	primed in situ hybridization
RFLP	restriction fragment length polymorphism

-TCTGCTAA-.

It is estimated that there are 10,000 to 100,000 genes in the human genome. Only approximately 10% of human DNA codes for genes (termed "unique sequence" DNA). Exons are the portions of the gene that code for protein; introns are non-coding regions within the gene that may have regulatory and promoter functions. Genes range from a few hundred base pairs to over 1,000,000. The remaining 90% of human DNA is comprised of "repetitive sequence" DNA, which serves no known function. Chromosomes are DNA in its most complicated form of coiling. There are normally 23 pairs of chromosomes in the human.

Mutations

Mutations within the gene (errors in the nucleotide sequences) may cause disease if they are in the exons or the regulatory portion of the gene. Mutations may be a single base change

Table 1. Autosomal Dominant Disorders

Adult polycystic kidney disease	Huntington disease
Achondroplasia	Marfan syndrome
Myotonic dystrophy	Familial colonic polyposis
Ehlers-Danlos syndrome, type I	Familial hypercholesterolemia
Neurofibromatosis	Noonan syndrome

Table 2. Autosomal Recessive Disorders

Alpha-1-antitrypsin deficiency	Phenylketonuria
Congenital adrenal hyperplasia	Hurler syndrome
Refsum disease	Cystic fibrosis
Sickle cell anemia	Homocystinuria
Tay-Sachs disease	Meckel-Gruber syndrome
Wilson disease	Thalassemia (alpha and beta)

Table 3. X-Linked Disorders

Duchenne muscular dystrophy	Hemophilia B
Ehlers-Danlos syndrome, type V	Hunter syndrome
Glucose-6-phosphate deficiency	Fragile X
Hemophilia A	Lesch-Nyhan syndrome
Hypophosphatemic (vitamin D-resistant) rickets	

(point mutations) or deletions of a single or multiple bases. The changes alter the quantity or qualitative function of the protein product.

Mutations are passed down to progeny. If a mutation on one chromosome causes disease, the disease is considered dominant. If mutations are required in the gene on both chromosomes, the disease is recessive. If the gene is on chromosomes 1-22, it is autosomal. If it is on the X chromosome, it is X-linked. (See Tables 1,2, and 3).

Molecular Genetic Technique

The technology of molecular genetics permits investigation of DNA sequences and mutations. Its rapid development continues to improve sensitivity of tests and decrease the time required to obtain results. The following tests are those most commonly used in prenatal diagnosis.

Polymerase Chain Reaction

For some genetic diseases, the mutations in the gene causing disease have been delineated and can be tested for, using "direct mutation analysis." The polymerase chain reaction (PCR) has helped make direct DNA testing possible. PCR is a simple, rapid method for synthesizing large quantities of DNA copies from very small amounts of DNA that can be derived from any nucleated cell. With PCR, two single-stranded short nucleotide strands (primers) are synthesized; primers are complementary to the regions flanking the gene of interest. The

primers are added to a PCR mixture, which includes a small amount of genomic DNA, the four deoxynucleotides (dATP, dCTP, dTTP, dGTP) and a heat-stable DNA polymerase (Taq polymerase), which drive the replication process (Figure 1).

The mixture is then placed in a temperature-cycling apparatus. The double-stranded DNA is rendered

single-stranded by heating the mixture to 94° C. Next, the temperature is lowered to 55-60°, allowing the primers to anneal to their matching target sequences. The temperature is then raised to 72° C, which is optimum for Taq polymerase activity; new DNA strands are then synthesized on the initial DNA template by the addition of complementary bases. The temperature is next raised to 94° C again, and the cycle is repeated. The process is automated and repeated 30-40 times, resulting in an exponential increase in the number of target sequences for study. Millions of copies of the target sequence are generated, depending on the number of cycles. Diagnosis can be rapidly made on this, now "amplified," sample of DNA by several techniques.

Mutation Detection in PCR Products

A. Dot Blots: Probes can be constructed that match the gene area in question (allele-specific probes or

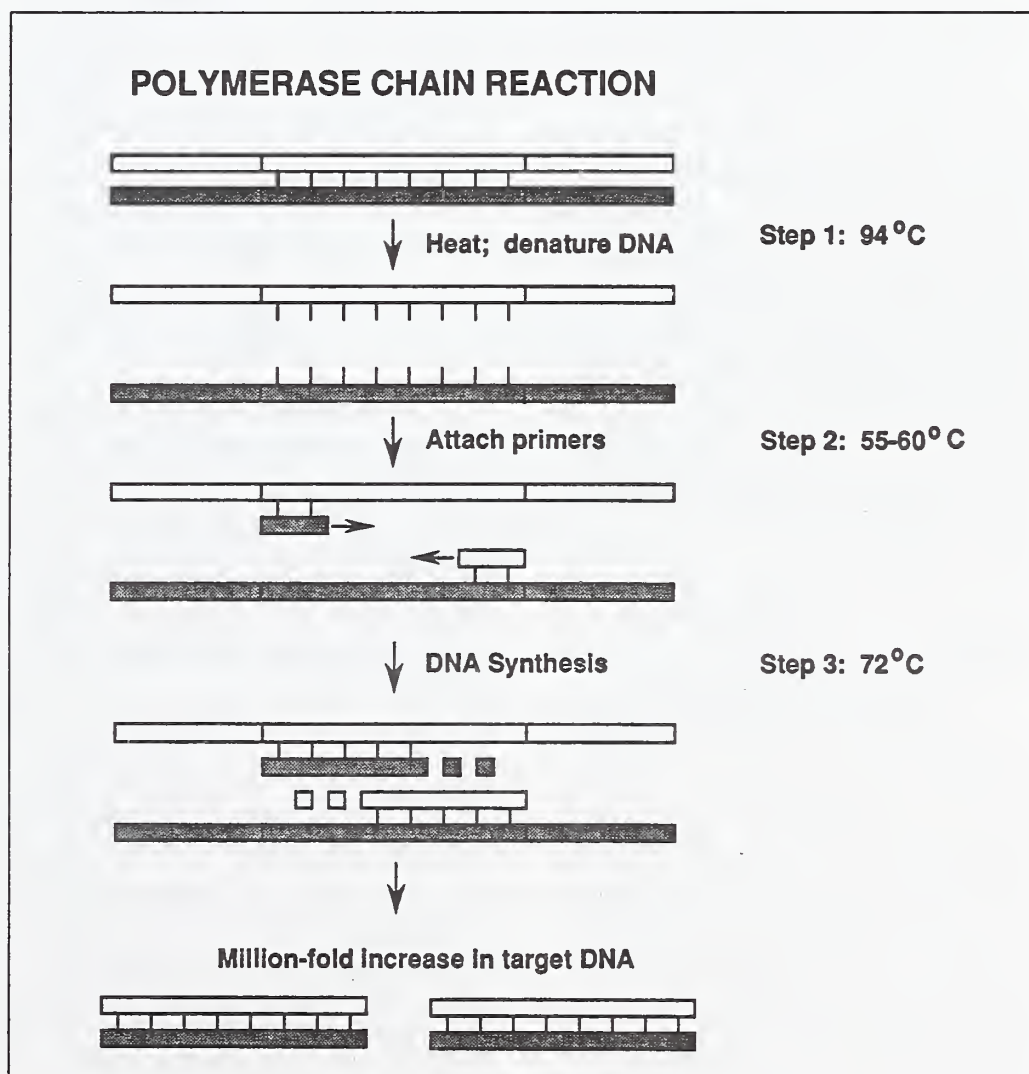


Figure 1: Polymerase chain reaction
 Step 1: Double-stranded DNA is heated and denatures into single strands;
 Step 2: Primers attach to gene-specific site; Step 3: DNA synthesis occurs with taq polymerase;
 Repeat all steps for 30-35 cycles.

ASOs). One probe will match a gene with a specific mutation; another probe will match only the normal gene. These are called dot or slot blots. Paper is impregnated with the amplified DNA and the probes are added. A color change would indicate a match. Testing with probes for the normal DNA strand and the mutated strand would give rapid information. ASOs are applicable to sickle cell disease, beta-thalassemia and many other genetic diseases.

B. Allele-specific primers: The primers used for PCR can be constructed to include the mutated area. If the primers are specific for the normal DNA and a mutation is present, no reaction will take place. The PCR product is introduced into an agarose gel and electrophoresed. The product is visualized under fluoroscopy. Some mutations such as in the cystic fibrosis gene are detected in this way (Figure 2).

C. Restriction enzymes: Bacteria use enzymes to protect themselves from viruses. These enzymes cut viral DNA at specific sites. For example, the enzyme produced by *E. coli* EcoRI cuts (restricts) all DNA where it recognizes the sequence GAATTC. This technology can be used if an enzyme is found that happens to cut at the site of a mutation. After PCR of the gene in question, restriction enzyme is added to the PCR product. The mutation is identified if 2 shorter fragments are seen on gel electrophoresis instead of one long strand.

Diagnosis by Genetic Linkage: Southern Blot Analysis

For many genetic diseases, the exact molecular basis is not known. Diagnosis can be made by an "indirect method" called linkage analysis. With linkage analysis, the disease-causing gene is tracked in the family by analyzing known DNA sequences closely linked to the gene or within the gene itself. To be informative, differences in these DNA sequences (known as polymorphisms) must exist between the mutated sequence and the normal sequence and be found in close proximity (or linked) to the gene of interest.

An example of linkage analysis is the original work with the sickle cell mutation. A polymorphism was found linked to the β -globin gene. The polymorphism could be identified with the restriction enzyme, Hpa I. Digestion with Hpa I results in a 7.6 kilobase (kb) fragment (restriction fragment length polymorphism or RFLP) when the normal β -globin A gene is present. When the β -globin sickle gene is present, the associated polymorphism involves a loss of the Hpa I restriction site, and a larger 13.0 kb RFLP results.

*For a patient with a
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disorder, area
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practitioners and
midwives can
call the Center at
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the status of prenatal
diagnosis or carrier
testing.*



RFLPs are detected by Southern blot analysis. A DNA sample cut with a restriction enzyme produces millions of fragments of variable sizes. These can be separated using agarose gel electrophoresis; when voltage is applied, the smaller fragments migrate in the gel faster than the larger ones. The fragments are then denatured (made single-stranded) and transferred (blotted) to a nylon filter; their position on the gel is thus preserved. The RFLPs of interest can be distinguished from the millions of other fragments by hybridizing the blot with a complementary single-stranded DNA probe specific for a DNA fragment within the RFLP. Radioactive labeling of the probe makes it possible to visualize the RFLP on a photographic plate after radiography. The RFLP appears as a

band; its position on the film indicates its speed of migration and thus its size. Southern blot analysis requires several days to complete. It also requires a relatively large DNA sample; therefore, the cells obtained from amniocentesis or CVS must be cultured, which may take several weeks.

For prenatal diagnosis of many disorders, including hemophilia A and B and some cases of thalassemia, indirect testing by RFLPs and Southern blot analysis is necessary. In disorders where the diagnosis depends on the size of the segment linked to a gene (such as Fragile X or Huntington's) Southern blot analysis is also utilized.

MOLECULAR CYTOGENETIC TECHNIQUES

Information can be gathered by examining a karyotype or photograph of the 46 chromosomes in a metaphase cell. However, beyond abnormalities of chromosome number and gross structure, new molecular cytogenetic techniques are required to detect abnormalities of individual genes on the chromosomes.

Fluorescence in situ hybridization (FISH)

FISH enables visual study of submicroscopic abnormalities on chromosomes that result in genetic disease. The normal gene sequence is defined and a probe, tagged with a fluorescent marker, is constructed to match that sequence. The probe is applied to a slide of a chromosome preparation or karyotype. If the normal sequence is present on both chromosomes, 2 signals will be seen in each cell. If the gene is missing or abnormal on one chromosome, only one signal will be seen in a cell. Williams syndrome, Prader Willi and DiGeorge syndrome are diagnosed by FISH.

Probes specific for each chromosome (usually the centromeric portion of the chromosome) allow for rapid analysis for trisomies. If trisomy 21 is present and a 21-specific probe is applied to a slide, 3 signals in every cell will be present. This analysis can be used on interphase cells. Thus, culture and metaphase preparations are

not necessary; FISH can be performed on uncultured amniocentesis cells (Figure 3). If probes for chromosomes 13, 18 and 21 are used with different color fluorescent tags, analysis for the common trisomies can be completed in 1-2 days. However, the sensitivity and specificity of FISH are not 100%; complete, routine karyotyping should always be performed. FISH is expensive and time-consuming; not all cytogenetic laboratories perform this technique. For these reasons, FISH will not soon replace conventional cytogenetic techniques.

Primed in situ hybridization (PRINS)

PRINS combines the techniques of FISH and PCR. Primers are applied to a cytogenetic preparation on a glass slide. Similar to conventional PCR, the primers anneal to target sequences and, in the presence of fluorescent-labeled nucleotides and Taq polymerase, extension of the DNA sequence occurs. The resulting signals can be visualized under fluorescent microscopy. Advantages of PRINS over conventional FISH include the speed of the process and lower costs. Furthermore, PRINS has a higher specificity for sequences found in the centromeres, allowing more accurate testing for trisomies.

**CLINICAL APPLICATIONS:
FRAGILE X AND CYSTIC FIBROSIS**

Hundreds of genetic diseases have been clinically identified. However, for only a fraction has the gene been mapped and mutations causing the disease been identified. Discussed below are 2 genetic diseases that obstetricians are likely to encounter.

Fragile X

Fragile X syndrome (FMR-1) is the most common cause of inherited mental retardation, seen in 1/1200 males and 1/2500 females. The range of IQs in males with Fragile X is similar to Down syndrome; females tend to be less severely affected. The disease is caused by an interruption of the FMR1 gene by a large repetitive sequence of trinucleotide repeat: CGGCGGCGG. From 6 to 50 trinucleotide repeats are normal. Female

carriers have between 50 and 200 repeats (premutations) and affected individuals have more than 200 (full mutations). Carrier testing is available by DNA analysis of the FMR1 gene. By PCR of the FMR1 gene, the number of trinucleotide repeats a woman carries can be determined. If she carries between 50 and 200 repeat sequences, she is at risk for affected offspring and should be offered prenatal diagnosis by amniocentesis or CVS, using PCR or Southern blotting.

Women with a family history of Fragile X or of undiagnosed mental retardation should be offered screening. This has been a subject of recent legal action. A woman with an uncle with undiagnosed mental retardation, a nephew with a behavior disorder or a son with autism are instances where a woman should be offered carrier testing. Although populations screening has been conducted on an investigational basis, it is currently not recommended. The vast majority of carrier females will have a family history of mental retardation.

CYSTIC FIBROSIS

Cystic fibrosis (CF) is the most common life-threatening autosomal recessive disease in North American Caucasians of European ancestry, with a frequency of 1 in 2500 live-births. The carrier frequency is about 1 in 25 individuals. CF results from a mutation in the gene that codes for the cystic fibrosis transmembrane conductance regulator, believed to control chloride ion conductance across epithelial cells. Clinical mani-

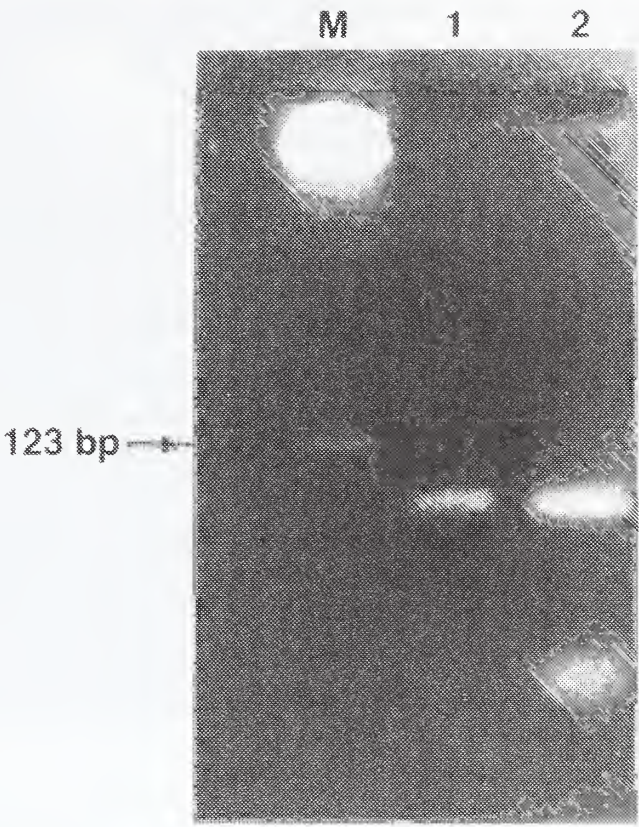


Figure 2: Ethidium bromide-stained agarose gel electrophoresis of PCR products. PCR was performed with allele-specific primers for normal CF gene (lane 1) and for $\Delta F508$ (lane 2), demonstrating the patient to be heterozygous. M designates the 123 base pair marker.

festations include meconium ileus, chronic obstructive lung disease, pancreatic insufficiency, liver cirrhosis, and failure to thrive. Diagnosis is made with the sweat test. The clinical course is highly variable, ranging from neonatal death to survival into the sixth decade. Advances in clinical care, which includes DNase therapy, have increased life expectancy. Individuals born today with CF are expected to survive into their thirties and forties.

In the United States, approximately 75% of CF mutations correspond to a 3 base-pair deletion, resulting in the loss of phenylalanine at amino acid position 508 in the coding region $\Delta F508$. Over 50% of people with CF can be expected to be homozygous (possessing 2 copies) for $\Delta F508$. However, over 400 CF mutations have been identified. This makes screening by way of mutational analysis difficult. By testing for 6 to 12 common mutations, it is estimated that 85% of CF carriers in the U.S. Caucasian popula-

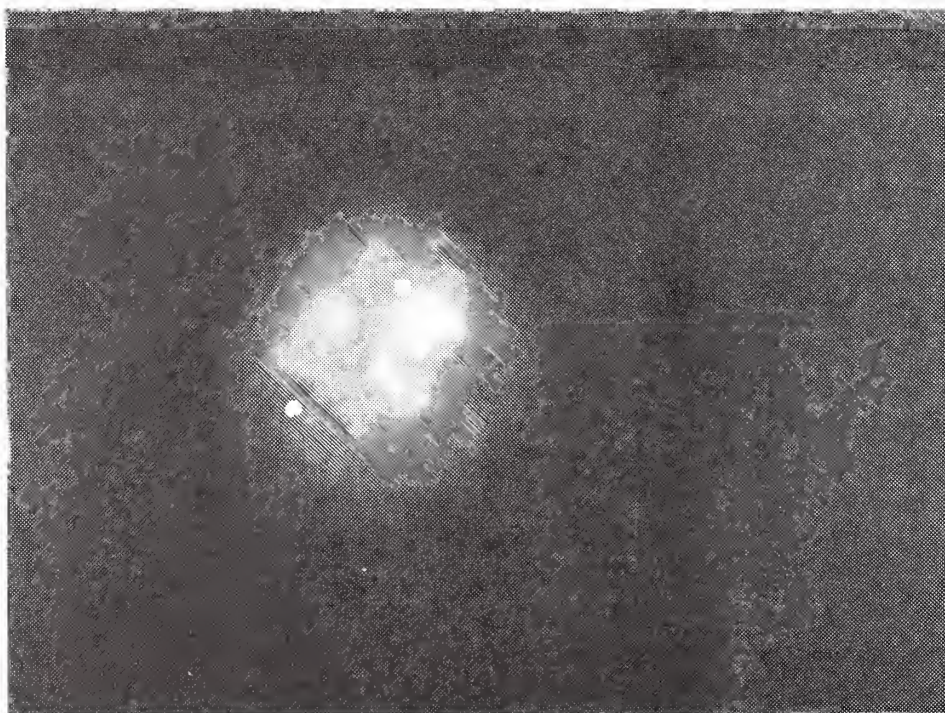
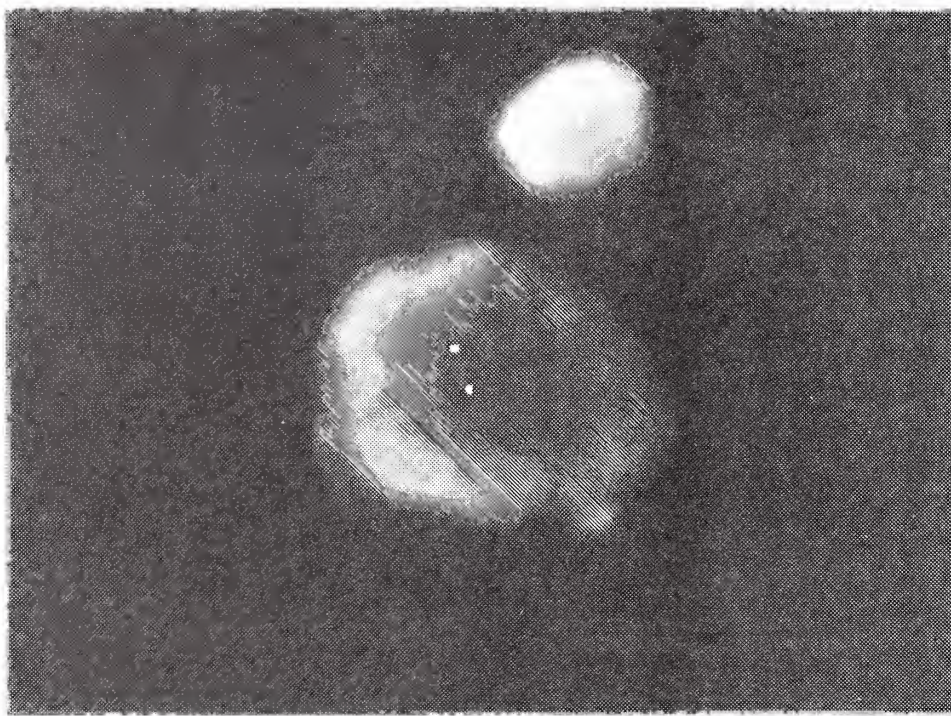


Figure 3: PRINS using 21-specific primers on interphase cells from amniocentesis. 3a: Normal cells; 2 signals. 3b: A case of trisomy 21, an interphase cell demonstrating 3 signals.

tion could be identified. The relatively low detection rate of carriers in the general population, coupled with the expense of testing, pretesting education and post-testing counseling, has kept population screening for CF from being recommended. However, many couples are concerned about CF. Below are several case scenarios the obstetrician may encounter.

A. Both parents carry a detectable CF mutation ascertained because of an

affected child. In this situation, prenatal testing would be expected to be close to 100% accurate in identifying an affected fetus. Prenatal diagnosis could be performed on DNA obtained by CVS or amniocentesis.

B. Parents of a child with CF with an undetectable mutation. Mutation analysis has been performed on the affected child. If a mutation is unidentifiable, linkage analysis with RFLPs and Southern blotting is necessary.

This is accomplished by identifying DNA markers on the chromosome that carries the CF gene. These markers can be tested for from fetal DNA obtained by CVS or amniocentesis and are highly accurate (97%+) in predicting whether the normal or mutant chromosome was passed on.

C. DNA from the affected child is not available. The parents would be screened (detecting 85-89% of CF mutations) for the common mutations. Linkage analysis would not be possible because there is no affected individual to test. If both parents carry a detectable mutation, then prenatal diagnosis is possible.

D. Relative with CF. This is the most common scenario encountered by the obstetrician. Carrier screening should be offered to individuals who have first- or second-degree relatives with cystic fibrosis. If the individual is found to be a carrier, carrier screening should then be offered to his/her spouse. If one parent has a detectable mutation and the other parent does not, prenatal diagnosis could not, at present, provide an unequivocal determination of fetal status.

FUTURE DIRECTIONS

Preimplantation Genetics

Another method for obtaining fetal DNA is by biopsy of the preimplantation embryo. In 1989, fetal sex was first determined in a human preimplantation embryo and in 1992, a molecular diagnosis was made when cystic fibrosis was excluded in an embryo. The diagnoses were confirmed at birth.

Following in vitro fertilization (IVF), a single cell (blastomere) is removed from the 4-8 cell embryo by micromanipulation. The target sequence in the DNA of the cell is amplified by PCR. Most centers involved in these investigational studies would urge women to undergo confirmatory prenatal diagnostic tests, such as CVS. Preimplantation diagnosis has been successful in diagnosis or exclusion of cystic fibrosis, Tay-Sachs disease, Lesch-Nyhan syndrome and hemophilia A. Analysis for chromosomal aneuploidy is also feasible by FISH.

Candidates for preimplantation genetic diagnosis are couples who require IVF to achieve a pregnancy and who are at risk for a single gene defect for which a reliable diagnostic test is available. Other couples who find pregnancy termination of an affected offspring unacceptable may also be candidates. Moreover, preimplantation diagnosis opens the door for genetic therapy in early gestation. Genetic repair of the embryo prior to transfer could presumably be accomplished with the introduction of a copy of the normal gene through a viral vector.

FETAL CELLS IN MATERNAL CIRCULATION

An exciting new field of research is the isolation of fetal cells from the maternal circulation and applying specific genetic testing to these cells. It has been shown that fetal cells exist normally in the maternal circulation in the first and second trimester. Most successful fetal cell isolation has targeted the fetal nucleated red blood cell. Antigens on the fetal cell surface serve as markers and can be used to separate these cells from maternal cells with flow-cytometry, electrophoresis or magnetic separation. The sorted cells are then placed on a slide and FISH is performed using chromosome-specific probes.

Research has not yet entered the clinical trial stage. Questions include: 1) What is the most efficient method of separating fetal from maternal cells? 2) Is there an optimal time for sampling? 3) What is the sensitivity and specificity of such testing? Would this method simply screen the patient and be an indication for invasive testing? Or would it be diagnostic? 4) Do fetal cells from a previous pregnancy persist? If the previous pregnancy was chromosomally abnormal, might these cells be detected?

CONCLUSIONS

Exciting breakthroughs for numerous genetic diseases occur with great frequency: the obstetrician should maintain a working relationship with either a geneticist, perinatologist or genetic counselor trained in prenatal

diagnosis. The Prenatal Diagnosis Center at Women and Infants Hospital is the only integrated program providing this expertise in southeastern New England. For a patient with a family history of a genetic disorder, area obstetricians, family practitioners and midwives can call the Center at (401) 453-7515 to find the status of prenatal diagnosis or carrier testing. Calls and messages will be returned by a genetic counselor and/or physician between 8 am and 5 pm, Monday through Friday.

Also invaluable is HELIX, the Directory of Medical Genetic Laboratories [(206) 527-5742]. This database catalogues all laboratories offering diagnosis of a genetic disease either on a clinical or research basis. However, it is highly recommended that the patient receive genetic counseling from a certified counselor and that specimens sent to laboratories be coordinated through the office of a geneticist or perinatologist.

Advances in our ability to diagnose disease on a molecular level and to offer safer and earlier methods of obtaining fetal DNA for study will continue to change obstetrical care. Research concerning non-invasive methods of obtaining fetal DNA (such as fetal cells in maternal circulation) and diagnosis of prenatal disease early enough in hopes of offering in utero genetic treatments are exciting. Finally, genetic testing is now offered only to women at high risk; in the future, this testing may be offered to all pregnant women.

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Screening for Birth Defects: Integrating Laboratory Evaluation, Genetic Counseling and Clinical Intervention

Jacob A. Canick, PhD, and Stephen R. Carr, MD

Prenatal screening for open spina-bifida, anencephaly, Down syndrome, and trisomy 18 in the early second trimester of pregnancy, using maternal serum alpha-fetoprotein (MSAFP) in combination with one or two other fetoplacental markers, has become standard in recent years. In 1985, the American College of Obstetricians and Gynecologists (ACOG) published a "Liability Alert" which stated that pregnant women should be offered MSAFP as a screening test for open neural tube defects. In 1994, the Committee on Obstetric Practice of ACOG published a "Committee Opinion" which recommended in part: "Women who are less than 35 years of age and who are between 15 and 18 weeks of gestation ... should be offered maternal serum screening to assess [Down syndrome] risk."^{1,2} A recent survey estimated that nearly two-thirds of pregnancies in the United States were screened in 1995, and that percent-age is increasing.³

But serum screening is not a laboratory test in isolation. Rather, it must be part of an integrated approach to prenatal care that includes timely implementation of laboratory testing, follow-up clinical testing, and professional genetic counseling. This review will describe a model of integrated prenatal screening and follow-up care; further reviews are listed in the references.⁴⁻⁸

DEVELOPMENT OF THE MULTIPLE MARKER SCREENING METHOD

Open defects

The fetal liver secretes large amounts of AFP into the fetal circulation and cerebrospinal fluid. An open defect results in direct exposure of fetal nervous tissue or vasculature to the amniotic fluid compartment causing leak-

age of AFP into the amniotic fluid. AFP diffuses from the amniotic fluid into the maternal circulation excessively in these conditions resulting in elevated maternal serum concentration of this albumin-like protein. By the early 1980s, the use of maternal serum AFP measurement in screening for open neural tube defects was well established. MSAFP measurement will result in the detection of the great majority of open spina bifida and anencephalic pregnancies, but can be reliably performed only between 15 and 20 gestational weeks

DOWN SYNDROME

Until biochemical screening became available, stratification of risk for Down syndrome pregnancy was based only on maternal age. Given the age distribution at childbirth, women in the U.S. have about a 1 in 650 midtrimester risk of carrying a fetus affected with Down syndrome. However, as a woman's age increases, so does her risk of having an affected baby so that, at age 35, the second trimester risk of Down syndrome pregnancy is about 1 in 270. This is comparable to the 1 in 200 risk of pregnancy wastage following second trimester amniocentesis and is commonly considered sufficient risk to justify invasive genetic testing. Risk continues to increase with age, so that screening by maternal age alone results in the identification of one case of fetal Down syndrome for every 140 amniocentesis procedures.

In 1984, based on the observed association of increased Down syndrome risk and lower MSAFP levels, MSAFP was combined with maternal age as a

Abbreviations Used:

ACOG	American College of Obstetricians and Gynecologists
BPD	biparietal diameter
hCG	human chorionic gonadotropin
LMP	last menstrual period
MoM	multiple of the median
MSAFP	maternal serum alpha-fetoprotein
uE3	unconjugated estriol

screening test for Down syndrome in younger women. The use of "low AFP" in women under the age of 35 together with the continued offering of amniocentesis to women who were 35 and older raised the overall detection rate of Down syndrome cases to about 40%, but it required offering amniocentesis to almost 10% of all pregnant women to achieve that level of detection. Using MSAFP in Down syndrome screening results in the identification of one case of fetal Down syndrome for every 100 amniocentesis procedures performed, a bit better than offering amniocentesis based on age alone.

Placental products tend to be elevated in Down Syndrome pregnancy, while products that are synthesized at least in part by the fetus (AFP) tend to be low in Down syndrome pregnancies. In 1987, research conducted at Women and Infants Hospital, the Foundation for Blood Research in Maine and the Medical College of St. Bartholomew's Hospital in London showed that the maternal serum level of the major estrogen of pregnancy, unconjugated estriol (uE3), was 27% lower in Down syndrome compared to unaffected pregnancy. uE3 is made in concert by the fetal adrenal, fetal liver, and placenta. At the same time, maternal serum concentrations of the placental hormone human chorionic gonadotropin (hCG) were

found to be elevated two-fold in Down syndrome compared to unaffected pregnancy. In 1988, research conducted in Rhode Island, Maine, and the United Kingdom described how the measurement of maternal serum hCG in conjunction with uE3 and AFP could better define the patient-specific risk for fetal Down syndrome than any method previously described. Within a short time, the use of multiple serum markers replaced AFP alone in prenatal screening.

THE MULTIPLE OF THE MEDIAN (MoM)

Maternal serum levels of each of the three analytes used in the triple test are constantly changing during the period of gestation, from 15 to 20 weeks, when screening is done. MSAFP levels increase at a rate of approximately 15% per week, uE3 levels increase at a faster rate of approximately 24% per week, and hCG levels decrease, not at a constant rate, but initially quite rapidly, leveling off by 18 to 20 weeks. In order to account for these changes, we establish median values for each day of gestation to serve as reference points in calculating an individual patient's results. By dividing that patient's AFP, uE3, and hCG levels by the appropriate day-specific medians, we generate three patient-

specific multiples of the median or MoMs. These MoMs enable us to compare patients to each other, and in so doing to establish population data that are no longer gestational-age specific. MoM values of these analytes in combination with maternal age are used to determine a patient's risk after testing as compared to her risk based solely on maternal age.

COMBINING MARKERS TO PROVIDE A SINGLE RISK ESTIMATE

The levels of AFP, uE3 and hCG in maternal serum are independent of maternal age and only weakly correlated with each other. This means that levels of all three analytes provide useful information for estimating risk. In 1988, we described a statistical method, conceptually similar to that widely used by genetics laboratories when screening with AFP alone, for combining all screening variables to calculate a single patient-specific risk. In fetal Down syndrome, AFP and uE3 levels are, on average, low; and hCG levels are, on average, elevated. But an individual case may not necessarily show such a pattern. Rather, one, two, or perhaps three analytes may be low or high, and when combined with the age-specific risk, the

estimated risk will most commonly be increased in an actual Down syndrome pregnancy. Thus, there are no "normal" or "abnormal" ranges for each marker. It is not always possible to visually inspect assay values to decide whether or not a woman is at high risk.

SCREENING PERFORMANCE

The detection rate and screen positive rate will be determined by the maternal age distribution in the screened population and by the risk cut-off that is selected.

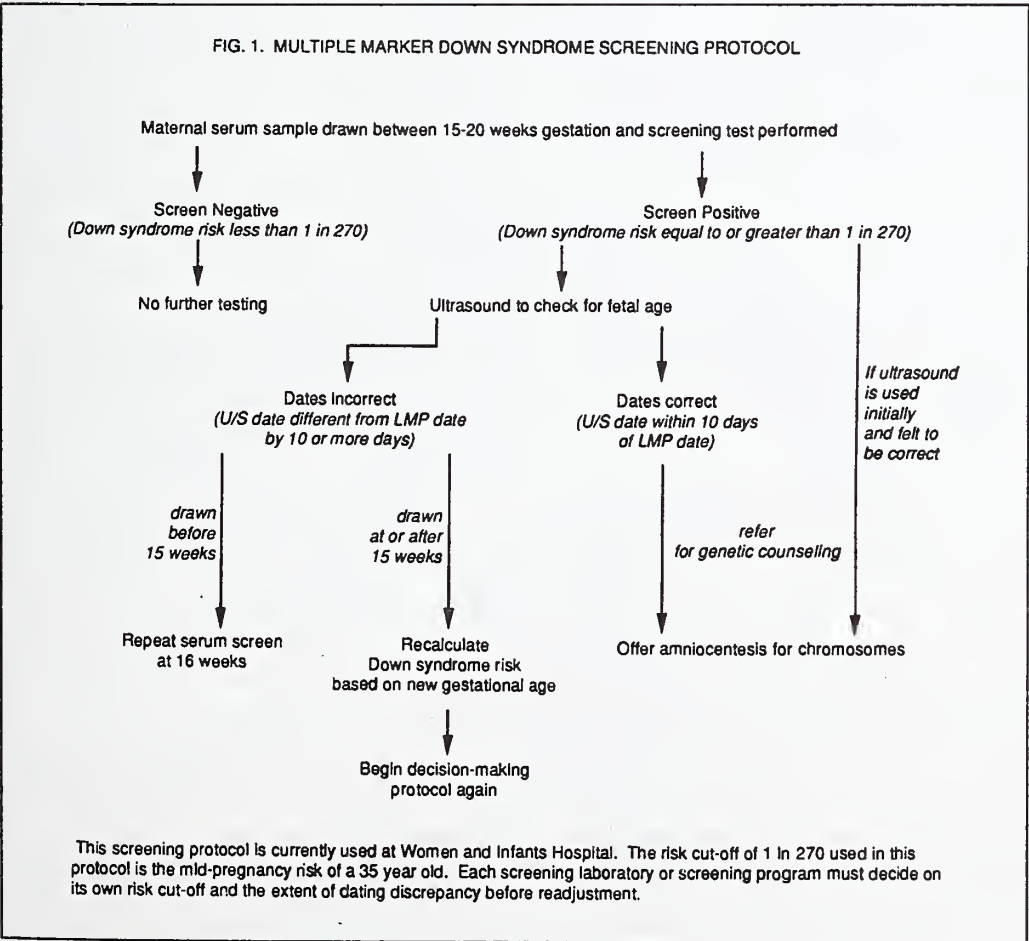
Maternal age

Maternal age is a risk determinant for Down syndrome pregnancy; as age increases so does risk. Therefore, a primarily younger population that has serum screening will have a lower a priori, age-related risk, and the result will be a lower detection and screen positive rate than if a primarily older population is screened. For example, 25 year olds have an age-related second trimester risk of 1 in 1200. If only 25 year olds were screened using the triple test, approximately 3% of these patients would be called screen positive and only 45% of all the Down syndrome cases in that age group would be identified among patients with positive screening test values. If instead, only 35 year olds, who have an age-related second trimester risk of 1 in 270, were screened, approximately 15% of these patients would be called screen positive and 75% of all the Down syndrome cases in that age group would be identified in patients with positive screening tests.

Risk Cut-off

Detection and screen positive rates obtained with the triple screen also depend on the risk cut-off. Many genetics programs use a second trimester risk cut-off of 1 in 190, the risk of a 37 year old woman. Other genetics programs use a risk cut-off of 1 in 270, the risk of a 35 year old. Once the risk cut-off has been established, its application to screening is clear: If a particular patient has the triple test and her risk is greater than that cut-off, she is screen positive and is offered follow-up testing. If another patient has a risk after testing that

FIG. 1. MULTIPLE MARKER DOWN SYNDROME SCREENING PROTOCOL



is less than the cut-off, she is screen negative and may not be offered further testing.

Taking this information, we can use as an example the population of pregnant women seen at Women and Infants Hospital between 1989 and 1991. The average age was 27 years; 5% of women were over the age of 34. Using a second trimester risk cut-off of 1 in 190, the detection rate would have been approximately 60% with a screen positive rate of 5%. We in fact used a second trimester risk cut-off of 1 in 270, and the detection rate was about 65% with a screen positive rate of 7.8%. The average age of our screened population has increased to close to 30 in recent years, so that now we would expect the detection rate to be closer to 70% and the screen positive rate closer to 9%.

THE TRIPLE TEST SCREENING PROTOCOL

The process of second trimester screening begins with a serum sample obtained between the 15th and 20th completed week of pregnancy (Figure 1). Ideally the sample should be obtained between the 16th and 18th week, the optimum time for open neural tube defect detection.⁴ The same sample is used for screening for open defects using the AFP assay and for Down syndrome using all analytes. The following information must be supplied to the laboratory with the sample:

a) An estimate of gestational age: If dating is by ultrasonography, the method of choice is first trimester crown rump length or second trimester biparietal diameter (BPD). BPD measurement will enhance screening for open spina bifida and will not be affected by fetal Down syndrome. Use of femur and humerus length should be avoided in dating, because a true Down syndrome fetus will have, on average, shorter long bones.

b) Date of birth, maternal weight, and maternal race: Maternal age is necessary to calculate age-specific risk for fetal Down syndrome; maternal weight is necessary to adjust for differences in maternal dilution of the screening markers; and maternal race is necessary to adjust for the higher AFP levels in the

black population.

c) Relevant information on patient or family history of open neural tube defects and chromosomal defects must be provided for proper analysis of patient-specific risk. Also maternal insulin-dependent diabetes mellitus should be noted, if present, because of the associated risk for open neural tube defects and because maternal serum AFP levels are about 20% lower than normal, on average.

Prenatal screening for fetal Down syndrome and open fetal defects in the second trimester has proven to be efficient in detecting the majority of affected pregnancies.



Samples are assayed within two working days of receipt and results reported out as soon as possible. Screen positive results (elevated AFP or positive triple screen) are called in to the care provider's office. At the time of the call, recommendations for appropriate follow-up procedures are made. All results (positive and negative) are printed as individual reports and transmitted to the care provider's office or clinic.

FOLLOW-UP PROCEDURES

A patient identified as screen positive should be counseled by someone with expertise in genetic counseling. The following follow-up procedures should be offered:

a) Confirmation of gestational dating by ultrasound determination of BPD. If a pregnancy is not as far along as originally thought, the triple screen result might be recalculated to be screen-negative if the new gestational age is still 15 completed weeks or more. Alternatively, the original sample may be found to have been drawn prior to 15 weeks, 0 days. If so, a new serum sample is obtained and the triple screen is done again.

A significant dating discrepancy

between that derived from LMP and that derived by ultrasound is decided by the individual screening program. Various programs select a discrepancy between 8 days and 14 days, greater than which they will adjust the MoM and risk results, based on the sonographic estimate of age. At Women and Infants Hospital, we use a discrepancy of 10 or more days.

b) If, after a check of gestational dating, the result remains screen positive, the patient should be counseled about the risk of fetal Down syndrome and offered amniocentesis.

WHO SHOULD HAVE THE TRIPLE SCREEN?

With the triple screen, maternal age is just one of four determinants of risk and can no longer be considered of prime importance. Therefore, all patients, regardless of age, are candidates for screening. Specific guidelines are as follows:

a) The Younger Patient: According to the 1994 ACOG committee opinion, all pregnant women in the United States under the age of 35 should be considered candidates for multiple marker screening such as the triple test.² This population represents the great majority of pregnant women for whom screening was previously not available.

b) The Older Patient: As described earlier, patients who are 35 or older are usually offered genetic amniocentesis. With the advent of the triple screen, older pregnant women can consider refining their risk of carrying an affected fetus before deciding whether to accept the risk of amniocentesis. When applied to the advanced maternal age population, the triple screen will identify 25% of these patients as screen positive (i.e., remaining at increased risk), and in this screen positive group, 90% of the cases of fetal Down syndrome will be found.¹³ Thus, 75% of all older patients will be reclassified as low risk and can avoid amniocentesis with no more than 10% of the Down syndrome cases being missed in this group.

Current ACOG guidelines recommend that all patients who are 35 or older be offered genetic amniocentesis. However, the ACOG guidelines state that if a woman wants to avoid the risk

of amniocentesis, she should consider having a serum screening test in order to make a more informed decision. The use of prenatal screening by older pregnant women is becoming more and more common: 9% of the women who had triple screens last year at Women and Infants were 35 and older.

DETECTING TRISOMY 18 AND OTHER DEFECTS

Trisomy 18 (also known as Edward's syndrome) is the second most common autosomal trisomy in newborns and its prevalence at term is 1 in 8000, approximately one-tenth the birth prevalence of Down syndrome. Trisomy 18 babies rarely live beyond one year and the majority die within days or weeks of birth. Indeed, most fetal trisomy 18 cases are spontaneously lost in utero. Therefore, prenatal screening for trisomy 18 would not be undertaken in and of itself but would be a useful adjunct to Down syndrome screening if it could be accomplished efficiently using the current Down syndrome screening markers.

In fact, the levels of the three analytes used in Down syndrome screen-

ing are all, on average, substantially lower than normal, with median levels for AFP, uE3, and hCG of 0.6, 0.4, and 0.3 MoM, respectively. Because hCG levels are low rather than high, trisomy 18 pregnancies would almost never be identified by a screening protocol designed to detect Down syndrome. However, separate protocols have been implemented with quite impressive results. It is, therefore, useful and highly efficient to screen for trisomy 18 using the triple test, and can be accomplished with appropriate risk calculating software.

Other chromosomal abnormalities may also be identified within a triple marker screening protocol for Down syndrome and trisomy 18. Among these are Turner syndrome (monosomy X) with and without concurrent hydrops fetalis, and triploidies with and without partial hydatidiform mole.⁸ Various obstetrical complications and adverse fetal outcomes have been found to be associated with abnormal levels of each of the three screening markers. However, until large controlled studies can be evaluated and effective obstetrical intervention determined, it is not yet appropriate to use

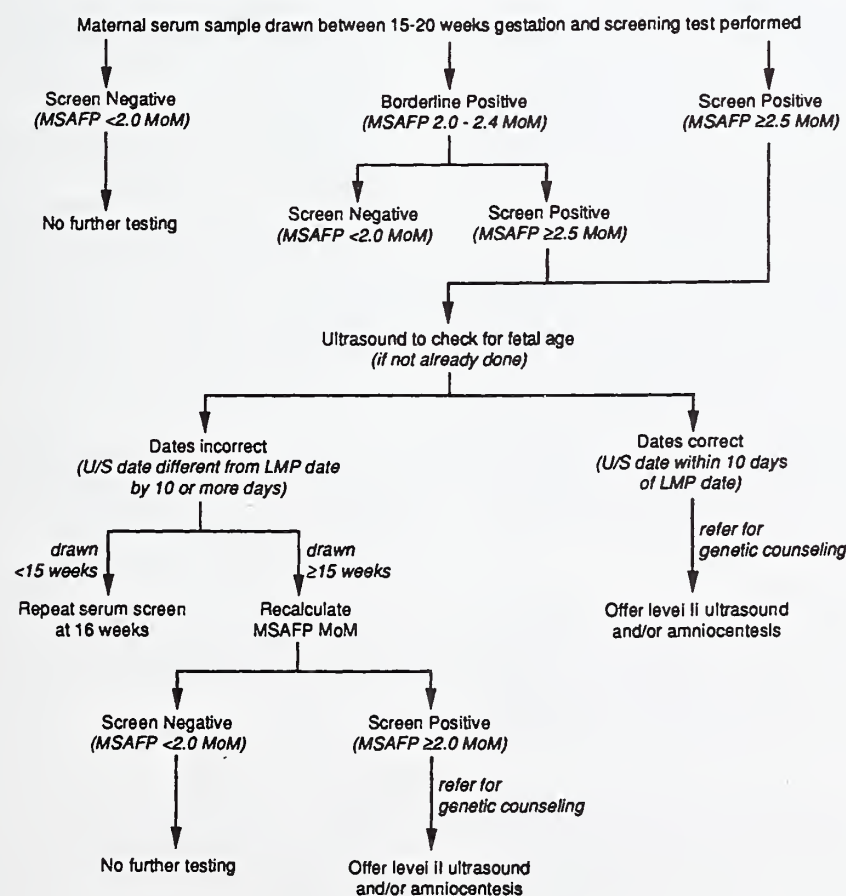
the triple test to alert physicians and patients.

SCREENING FOR OPEN FETAL DEFECTS

As described earlier, levels of maternal serum AFP are usually markedly elevated in cases of open fetal defects: median AFP levels in anencephaly, open spina bifida, gastroschisis, and omphalocele are 7.4, 12, and 6 MoM, respectively. At a fixed 5% screen positive rate, the detection rates are approximately 85%, 95%, 95%, and 60%, respectively. Most commonly, a fixed maternal serum AFP cut-off of 2.0 or 2.5 MoM is established as the point at or above which a patient is screen positive. At Women and Infants (Figure 2), the more conservative 2.0 MoM cut-off is used. If the initial sample value is between 2.0 and 2.4 MoM, this is considered a borderline screen positive result and a repeat serum sample is generated one week later. If the initial sample is 2.5 MoM or greater or if the repeat sample is 2.0 MoM or greater, the patient is counseled about follow-up testing. As is true in screening for Down syndrome, the first consideration is that the result was screen positive because the gestational dating estimate was wrong. Ultrasound dating by BPD is recommended to rule out anencephaly and to optimize screening for open spina bifida. If the ultrasound date is discrepant by more than that established by the screening program, the sonographic estimate of gestational age is used and the MoM is recalculated.

If the patient continues to be screen positive, the risks and benefits and accuracy of the diagnostic tests (targeted (level II) ultrasound and amniocentesis) are described. Ultrasound is non-invasive and is increasingly the test of choice for open fetal defects. Alternatively, amniotic fluid analysis of AFP levels and the presence of the neuronal marker, acetylcholinesterase, are well established as the most accurate diagnostic test for open fetal defects. Although amniocentesis is invasive and carries a risk of miscarriage, it also allows for fetal karyotype analysis, which is frequently abnormal in cases of open spina bifida and omphalocele.

FIG. 2. OPEN NEURAL TUBE DEFECT SCREENING PROTOCOL



This screening protocol is currently used at Women and Infants Hospital. Please note that the MoM cut-off used is 2.0. Most programs use a cut-off of either 2.0 or 2.5 MoM. The action point for a discrepancy between last menstrual period and ultrasound dating is ≥ 10 days.

RECENT ADVANCES IN BIOCHEMICAL SCREENING

The current screening methods, while markedly better than what could be done in years past, still leave room for improvement in sensitivity and specificity. Luckily, improvements appear to be imminent. Closest to introduction is a new maternal serum analyte which would be added to the current second trimester screening protocol. The new marker is inhibin-A, a protein hormone synthesized by the placenta. Its levels are almost two times higher in cases of Down syndrome than in unaffected pregnancies, much like hCG. It has been shown to add about 7-9% more detection to triple marker screening and as much as 22% to double marker screening. While the use of inhibin-A will improve screening for Down syndrome, inhibin-A levels in Edward's syndrome do not appear to be abnormal, so the new marker is unlikely to improve screening performance for that trisomy.

The ability to screen for Down syndrome earlier in pregnancy than is now possible, as early as 10 gestational weeks, appears to be becoming a reality. In fact, data now indicate that the best screening test for Down syndrome may be a new type of triple test offered in the first trimester. The new test would consist of two maternal serum markers, free β -hCG and PAPP-A, a very large subunit protein synthesized by the placenta, and an ultrasound marker, nuchal translucency. Together, the three markers may achieve a detection rate approaching 90% while calling about 5% of pregnant women screen positive. The two serum markers used alone appear to achieve a 60% detection rate at the same screen positive rate, which is not an improvement over current or future second trimester screening performance. A variety of practical problems may complicate implementation of first trimester screening, among them early identification of abnormal pregnancies destined to be lost before term, inability to screen for open fetal defects in the first trimester, and issues of availability and safety of the first trimester diagnostic procedure, chorionic villus biopsy.

COMPLEMENTS TO BIOCHEMICAL SCREENING FOR FETAL DEFECTS

The preceding discussion has chronicled our improving ability to use the

biochemistry laboratory to detect women at increased risk for fetal anomalies. Those biochemical assays do not function by themselves, however. Several points merit emphasis:

a) Any time a screening test (be it biochemical, ultrasound or other) indicates a particular pregnancy is at greater than usual risk for fetal anomaly, it is essential that competent, professional, non-directive, genetic counseling be provided. (See article by Deedy Hamer, this issue).

b) Second trimester targeted ultrasound offers an attractive, though presently ineffective, alternative to invasive testing for aneuploidy. A number of "soft" ultrasound findings that are relatively more common among fetuses affected by Trisomy 21 have been identified and have been used to modify, post hoc, the risk generated by the triple screen described above. These include shortened femur and humerus, increased nuchal thickness, pyelectasis, and echogenic bowel. Their contribution to detection of aneuploidy remains controversial, especially in cases where no anatomic abnormalities are present. Patients requesting only ultrasound evaluation for detection of aneuploidy should understand that not all aneuploid pregnancies will present with anomalies that are detectable by ultrasound, and that it is impossible to provide accurate estimation of the detection and screen positive rates using sonography alone.

c) The ability of ultrasound to detect fetal anomalies depends on their prevalence in the population under study. In unselected populations, i.e. when ultrasound is used in a screening fashion, the better trials have determined 35-55% sensitivity and >99% specificity. When performed on referral populations, i.e. populations already determined to be at increased risk, sensitivity of >95% with specificity of >90% has been determined.

CONCLUSIONS

1) Prenatal screening for fetal Down syndrome and open fetal defects in the second trimester has proven to be efficient in detecting the majority of affected pregnancies.

2) Additional chromosomal abnormalities are also identified through screening.

3) Efforts continue to identify new markers which may further enhance second trimester screening and will allow screening earlier in pregnancy.

4) Until noninvasive antenatal diagnostic tests become a reality, prenatal screening will provide the most practical method of identifying those women for whom invasive diagnostic procedures are warranted.

5) Ultrasound offers technology that complements, but does not replace biochemical screening and invasive testing.

6) Genetic counseling is an essential and irreplaceable part of screening and diagnosing of fetal defects. Without counseling, the available technology could lead to uninformed decisions that will profoundly alter patients' lives.

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Preventing Birth Defects: The Challenges of Diabetic Fetotherapy and Neural Tube Defects

Marshall W. Carpenter, MD

Maternal-Fetal Medicine has its clinical roots in prenatal diagnosis. As the obstetrical care focus has evolved from a primary objective of maintaining maternal health to a view that includes fetal well-being, the principles of maternal and fetal physiology and pathology have been applied increasingly to clinical care. This transition has been accelerated by the advent of technologies such as ultrasonic imaging, biochemistry, molecular genetics and cytogenetics. In prenatal diagnosis, each technology has reinforced the utility of the others, so that screening for fetal disease has become an increasingly important part of routine antenatal care.

The detection and prevention of diabetic fetopathy and neural tube defects are particularly salient examples of the power of these technologies. Both types of lesions are fairly common compared to other fetal defects. The incidence of fetal structural defects at birth in women with chronic diabetes has been about 10% or about 3-fold that of the general population. Neural tube defects occur in as much as 1% of births in Ireland and Wales and in about 0.2% of pregnancies in the eastern United States.

Both classes of defects have a multifactorial inheritance. In vitro studies confirm that diabetic fetopathy, a varied group of anatomic malformations, is most likely secondary to high concentrations of ambient glucose, and probably reflects a disturbance in cellular migration and tissue differentiation in the early embryonic period (up to 56 days after conception). Several epidemiologic studies strongly suggest that maternal hyperglycemia during the embryonic period results in a higher risk of birth defects in these pregnancies and that the early normal-

ization of maternal glycemia reduces this risk. Yet the ethnicity of diabetic women also seems to affect the relative proportion of the types of fetal anatomic defects associated with maternal diabetes.

Neural tube defects (NTD), occurring at day 22-29 of the embryonic period, also has a multi-factorial inheritance. Fetuses with a primary relative affected with NTD have a 20-fold increase in their risk. Though drugs such as folate antagonists are associated with these defects, only 10% of affected offspring are born to women with risk factors such as a positive family history for NTD.

Both classes of defects are associated with high degrees of chronic morbidity. Diabetic fetopathy may involve most organ systems. Cardiovascular, skeletal, gastrointestinal, genitourinary, central nervous system and facial defects are found in increased numbers in pregnancy complicated by maternal diabetes (Table I). Neural tube defects present equally as lethal anencephaly or as spina bifida. Among infants with spina bifida as many as 15% may have other defects and as many as 10% may have chromosomal abnormalities. Case series from the 1960s report that infants born with open (non-skin covered) spina bifida may be expected to suffer a mortality rate of 11-35% depending on the lesion's level and major morbidity in 70-80% of survivors. Though survival of live-born infants has improved, the high rate of morbidity among survivors has not. Common types of associated morbidities include brain stem herniation and respiratory difficulties (often occurring later in life), cognitive deficiency, recurrent osteomyelitis, recurrent upper urinary tract infections with renal failure, incontinence, hydrocephalus requiring shunting, and limited mobility.

Abbreviations Used:

AFP	alpha-fetoprotein
MoM	multiple of median
NTD	neural tube defect

All limit the ability of the affected individual to live independently.

The Prenatal Diagnosis Program at Women and Infants Hospital and its AFP screening program, in particular, offers an integrated approach to management of women at risk of having fetuses affected by anatomic and other defects. The Program provides education about its screening tests for patients and physicians, interpretation support for physicians' offices, genetic counseling, sonographic evaluation of

Table 1: Congenital anatomic defects in infants of diabetic mothers

Skeletal:	Sacral agenesis (caudal regression)
	Limb defects
Central nervous system:	Anencephaly
	Spina bifida
	Microcephaly
Renal:	Renal agenesis
	Hydronephrosis
	Ureteric abnormalities
Cardiovascular:	Transposition of the great vessels
	Ventricular septal defect
	Atrial septal defects
	Coarctation of the aorta
	Cardiomyopathy
	Single umbilical artery
Gastrointestinal:	Duodenal atresia
	Anorectal atresia
	Small left colon syndrome

at-risk fetuses, access to pediatric care providers for further counseling in cases of confirmed abnormalities, follow up for parents who choose to continue an affected pregnancy, and abortion counseling, procedures, and bereavement support for those electing to terminate an affected pregnancy. This integrated environment provides for expeditious and humane evaluation of patients and timely feedback for managing physicians. However, a significant public health effect of such a program is only possible in the context of a reliable and sensitive screening process that identifies a significant proportion of these particular defects.

SCREENING AND DIAGNOSIS OF FETAL DEFECTS

The combination of high incidence and high degrees of associated morbidity means that screening programs with sufficient sensitivity to identify women at risk for these defects may result in decreased perinatal morbidity and care costs. The presence of diagnosed diabetes mellitus in a pregnant patient may be used as a screening tool for diabetes-related fetal defects. Most women who have pre-gestational hyperglycemia (estimated to be as high as 2-5% in the United States) have an established diagnosis of Type 2 diabetes mellitus. Approximately 0.1 to 0.5 percent of pregnancies are complicated by Type 1 (insulin dependent) diabetes. About half of Type 2 patients are undiagnosed, however, and may not be identified except during third trimester screening in pregnancy. Because of the established diagnosis, these women are already segregated as being at risk for diabetic fetopathy.

Elevated levels of glycated hemoglobin (hemoglobin A1c) have been demonstrated to correlate with average glycemic levels over a period of three to four weeks. In addition, first trimester hemoglobin A1c has been associated with risk of fetal defects in diabetic gravidas. Pregnancies with values <8.5% have risk of birth defects comparable to non-diabetic pregnancy. Those with greater values have an aggregate birth defect risk of 20% with increased risk in those with higher glycated hemoglobin values. Consequently, we believe that, in the first or early second trimesters, diabetic gravidas

should be offered glycated hemoglobin testing to help stratify risk for fetal defects. However, those with lower values still remain at unknown risk since significant hyperglycemia present for only short periods of time during embryogenesis may still result in fetopathy without significant effects on subsequently measured hemoglobin A1c.

... "success" in a screening program for fetal defects is, by nature, of limited value since its result is only the identification of an anomalous fetus. This provokes an arduous and heart-rending process on the part of the parents to come to terms with the disposition of the pregnancy.



We offer genetic counseling of diabetic gravidas at approximately 15 weeks to exclude other genetic issues that may need clarification and/or additional diagnostic evaluation. If elected by the patient, we perform fetal anatomic evaluation, including fetal echocardiography by 22 weeks gestational age, at which point the fetus is large enough for optimal anatomic evaluation. The great variability of anatomic defects in diabetic fetopathy limits the diagnostic sensitivity of sonography, however. Approximately 80% of fetuses with defects may be identified but only 40% of defects will be confirmed prior to birth.

A successful screening model for identifying pregnancies affected with neural tube defects has also been established. In 1972 Brock and Sutcliffe¹ demonstrated that a normal, albumin-like fetal plasma protein called alpha-fetoprotein was found in higher concentrations in amniotic fluid in fetuses with open neu-

ral tube defects compared to that of unaffected controls. With the advent of more sensitive radioimmunoassay techniques capable of detecting ng/ml concentrations in maternal serum, large scale prospective studies established that this assay, performed at 16 to 22 weeks, is capable of identifying 90% of fetuses affected with open NTD and approximately 75% of ventral wall fetal defects if a screening threshold of 2.0 multiples of gestational age-specific medians (MoMs) is selected. This will result in a positive screening test rate of 5%.

Women and Infants Hospital was one of the earlier programs in the United States to begin a population-based screening program for fetal open defects in 1983. Because the Women and Infants Hospital AFP laboratory participates in a nation-wide quality control program, it has demonstrated the same high sensitivity for this defect while minimizing the number of positive screening tests. As others, we have found that, after correction of misdated pregnancies and exclusion of multifetal pregnancies, stillbirths, and fetuses with anencephaly by routine sonography, about 1-2% of gravidas will be identified as having an overall risk for open neural tube defects of approximately 10%. Patients identified at high risk for NTD are offered genetic counseling and, if desired, subsequent sonography or amniocentesis. Sonography will identify more than 90% of spina bifida lesions. Amniocentesis is often used to confirm a suspected open neural tube defect. If additional defects are found in a fetus with spina bifida, chromosomal abnormalities are more probable. In this circumstance amniocentesis can also be used to obtain the fetus's karyotype.

PREVENTION OF FETAL DEFECTS

Success in a screening program for fetal defects is, by nature, of limited value since its result is only the identification of an anomalous fetus. In an arduous and heart-rending process, parents must come to terms with the disposition of the pregnancy. Consequently, we believe that all patients offered such screening in the course of routine obstetrical care may legitimately choose to decline testing, to avoid the difficult choices inherent in such testing. For the same reason, later in this

screening path, when screen-positive gravidas present to the Prenatal Diagnosis Center of Women and Infants Hospital for genetic counselling, one of the options always offered to patients is to decline further evaluation. Couples faced with the diagnosis of a complex and morbid fetal defect find themselves in the nexus of pain and uncertainty that characterizes much of the debate about abortion, specifically, and the meaning of persons at the extremes of life, generally. Clearly, prevention of fetal defects is to be preferred.

Several observational cohort studies have demonstrated that early intervention to achieve careful control of glycemia in women attempting or recently achieving conception will reduce the probability of fetal defects by 50 to 90%,² to that of the non-diabetic population. Several attempts at identifying and enlisting diabetic women of childbearing age in this process has met with mixed success. Rates of patient enlistment prior to conception have been reported between 20 and 70% in geographically defined populations. Enlistment is limited, in part, by patient denial that commonly provides a means of coping with the burdens of morbidity and social marginalization that often accompanies juvenile diabetes. The costs of pre-conception patient education programs is probably substantially less than the treatment of affected pregnancies and offspring. The per-patient cost of pre-conceptional education and treatment has been estimated to be \$3700, representing a 27% increase over the usual prenatal care for these patients. But when the costs of adverse maternal and neonatal outcome treatment are factored in, this intervention has been estimated to achieve a care cost savings of over \$1700 per enrolled patient for a benefit-cost ratio of 1.86.³ Despite these estimates, most insurers do not pay for pre-conceptional metabolic management of diabetic women.

The incidence of neural tube defects can also be reduced by pre-conceptional intervention. In 1986, Smithells, et al⁴ performed a controlled trial of multivitamin supplementation to women at risk for fetal neural tube defects. They found that folate supplementation, even in gravidas without demonstrable folate defi-

ciency, reduced the incidence of subsequent NTD. Large trials in both at-risk and unselected groups of gravidas have demonstrated that increased folate intake reduces the incidence of these defects by 73% and 48%, respectively. Consequently the Centers for Disease Control as well as the American College of Obstetricians and the American Academy of Pediatrics have joined in advocating that low risk women increase their folate intake by 0.4 mg and those at risk by 4.0 mg daily beginning at least one month prior to conception and continuing for the first three months of pregnancy. However, surveys continue to show that only a minority of women of childbearing age are aware of the benefits of periconceptional increased folate consumption. Several observers have suggested that the best means of increasing intake of a substance in the general population is by fortifying flour. Fortification of grain with folic acid (at 70 µg folate per 100 grams of grain) will replace the folate lost by the refining of flour. Its use is controversial, however, because of the associated risk of masking pernicious anemia in the general population. As yet, folate fortification of flour has not been widely mandated.

Consequently, effective intervention to achieve reduced incidence of both classes of defects requires the education and enlistment of all women of childbearing age to control the timing of their pregnancy. In the United States most asymptomatic women contact primary care physicians only after conception. Often years elapse between public health mandated contact with health care providers and a woman's next health maintenance conference with a physician or nurse. For these women, a public health educational initiative involving manufacturers of women's hygiene and cosmetic products may provide information about contraception and pregnancy health including that of birth defects prevention.

For those women of childbearing age who do seek health care, their access is most commonly to primary care physicians in the specialties of pediatrics, family practice, obstetrics and gynecology, and internal medicine. As yet, however, most professional organizations representing these specialties do not have guidelines

describing reproductive counseling that should be provided to non-diabetic and diabetic adolescents and young adults. Development of physician curricula for specialty board examinations, professional society-developed packaged information for patient use developed by professional societies, and guidelines for patient counseling would help raise the expectations of women for fertility control and birth defects prophylaxis.

Young female patients with diabetes are a special group. They are not only at great risk for preventable birth defects but are easily identified by physicians, nurses, pharmacists, insurers and health care vendors. The opportunity for education of these patients by any and all who contribute to their care is great. Successful enlistment of these women in their fertility control and metabolic care has the potential to reduce maternal morbidity, birth defects, and perinatal morbidity and mortality.

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Prenatal Diagnosis: The Role of the Genetic Counselor

Deedy Hamer, MS

Genetic counselors work at the crossroads where the provision of medical information may forever change the lives of our patients. Nowhere is this crossroads more evident than in a prenatal diagnostic center, where an integrated, multi-disciplinary team approach to the management and treatment of the fetus with anomalies is available. Staffing typically includes perinatologists, clinical geneticists, genetic counselors, sonographers, nurses, and social workers. This review will provide an overview of genetic counseling in the prenatal setting.

GENETIC COUNSELING DEFINED

The American Society of Human Genetics defines genetic counseling as: "a communication process which deals with the human problems associated with occurrence, or the risk of recurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family to 1) comprehend the medical facts, including the diagnosis, clinical course, and the management of the disorder; 2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; 3) understand the alternatives for dealing with the risk of recurrence; 4) choose the course of action which seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and... 5) make the best possible adjustment to that disorder in an affected family member and/or to the risk of recurrence of that disorder."¹ In prenatal diagnosis, genetic counselors educate patients by providing them with the facts and practical aspects of prenatal testing, as well as exploring the accompanying emotional and psychological sequelae.

BRIEF HISTORY

Genetic counseling is a relatively new profession; the first graduate program was established at Sarah Lawrence College in 1969 to address the educational and counseling needs of families with genetic diseases. Currently, 22 genetic counseling graduate programs provide students with a foundation in clinical and molecular genetics, as well as training in the psychological, cultural, and ethical attributes of counseling. Genetic counselors have completed a two year Master's degree program from an accredited program. They come from a variety of professional backgrounds: genetics, biology, psychology, social work, laboratory science, nursing, and public health. Many have gained board certification through the American Board of Genetic Counselors.

Genetic counselors work in varied settings, including prenatal, pediatric, and adult clinics, as well as in molecular and cytogenetic laboratories. Genetic counselors in state and federal agencies participate in shaping health policy for genetic services. Many counselors work as part of a health care team under the supervision of a medical ge-

Abbreviations Used:

DNA deoxyribonucleic acid

neticist. Today the majority of genetic counselors are employed in prenatal settings. However, the rapid expansion of genetic information is likely to result in new clinical applications of genetics, thereby increasing the demand for counselors specializing in single-gene disorders or predisposition to late-onset genetic disorders.

For example, individuals with a strong family history of breast or ovarian cancer may desire genetic counseling to learn more about testing to identify BRCA1 or BRCA2 gene mutations. Individuals identified as mutation carriers are at significantly increased risk to develop breast and/or ovarian cancer during their lifetimes.² The use of these data raises issues such as the utility of population-based screening, clinical decisions in BRCA1/BRCA2 positive individuals and access to this information by employers and insurers. Still unresolved is the efficacy of treatment, such as prophylactic mastectomy/oophorectomy or increased surveillance for BRCA1 or BRCA2

Table 1: Indications for Prenatal Genetic Counseling

Advanced maternal age	Multiple miscarriage or infertility (following initial evaluation)
Abnormal screening test results (e.g., maternal serum AFP tests)	Previous stillbirth or neonatal death
Sonographic findings of fetal anomaly	Consanguinity
Family history: mental retardation	Teratogen exposure
Family history: genetic disorders (e.g., cystic fibrosis)	Maternal diabetes-related risk of birth anomalies
Family history: congenital disorders (e.g., heart defect, cleft lip/palate)	Family history: cancer, mental illness, and cardiovascular disease
	Maternal questions/anxiety
Ethnic risk factors	
*Ashkenazi Jewish or French Canadian - Tay Sachs disease	
*African American, Hispanic, Mediterranean, Arab, Indian, Pakistani - hemoglobin S and hemoglobin C, and beta thalassemia	
*Southeast Asian, Mediterranean, Chinese - alpha and beta thalassemia	

Table 2. Key Aspects of Genetic Counseling

- Educate the patient about counseling expectations.
- Recognize the "crisis" provoked by the diagnosis.
- Ensure accurate information is given to the patient.
- Adapt communication to patient needs.
- Provide emotional support and validate patient feelings.
- Address the patient's questions about reproductive options.
- Facilitate decision making.
- Reinforce patient decision making capacity by helping her apply her experience, knowledge, and values toward reaching clinical decisions.
- Facilitate timely referral for services based on patient decisions.

mutation carriers. Women who test negative for BRCA1 or BRCA2 continue to face an 11% lifetime risk to develop breast cancer; thus, a negative test result does not eliminate the risk. Individuals seeking predisposition genetic testing for adult onset disorders should be made aware of these issues so that they may make an informed decision about testing. (See Table 1 for other common indications for referral for genetic counseling.³)

A TYPICAL PRENATAL GENETIC COUNSELING SESSION

Consider the case of a 25 year old gravida 2, para 1 woman whose maternal serum triple marker screen (e.g., AFP Plus) has placed her fetus at increased risk for Down syndrome. After receiving her results, often via a telephone call from her obstetrician, family practitioner, or nurse midwife, the patient may be referred to a genetic counselor.

Contracting

Once the screening test results have raised a question about the status of the fetus, patients may understandably be anxious, angry, or confused. Commonly the patient does not understand clearly the purpose of genetic counseling. Some patients may believe that "genetic counseling" is for individuals or families with a known genetic disorder. The first moments of a counseling session, termed contracting, usually focus on helping the patient understand the purpose of counseling, the indication for referral, and the session's dis-

cussion focus. The genetic counselor invites the patient to describe her fears and expectations about the session, and explains how genetic counseling may (or may not) meet those expectations. The tone and goals of the session are mutually established. This rapport fosters an open dialogue.

The American Society of Human Genetics defines genetic counseling as: "a communication process which deals with the human problems associated with occurrence, or the risk of recurrence, of a genetic disorder in a family."



Information Giving

The counselor explains the natural history of disease, its pattern of inheritance, its risk of occurrence/recurrence, available tests, and their inherent risks, benefits, accuracy and limitations. In the case presented, the

counselor would describe maternal serum screening for Down syndrome, and review the patient's screen positive results, including the change in her a priori risk. The counselor would discuss chromosomes, genes, and meiotic non-disjunction, using karyotypes to illustrate the extra 21st chromosome. The counselor would describe the cognitive function and physical features of individuals with Down syndrome. S/he would discuss amniocentesis in full, including its risks, potential benefits, and limitations. Patients have opportunities to ask questions; the counselor clarifies information, in language that the patient can comprehend, choosing words that do not imply parental failure or responsibility for the fetal defect, and do not suggest that the patient is "defective." For instance, words like "non-working gene," or "gene change," versus "abnormal gene," may be perceived as more neutral.

The Genetic History

The pregnancy and family history constitutes the preliminary genetic history of the pregnancy. This gives the genetic counselor a better understanding of the family's medical history so that risk assessment and additional testing, if indicated, may be offered. The family history may reveal birth defects or other conditions which may be detected prenatally. For instance, the patient's husband may have a congenital heart defect. In such cases, further testing, such as fetal echocardiography, may be offered because of increased fetal risk. When the family history is positive for a genetic disorder or birth

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defect, an accurate diagnosis confirmed by medical records is essential for specific risk assessment. Without a confirmed diagnosis, risk assessment is not reliable.

Patient Decision Making

Frequently the patient confronts a decision - a process facilitated but not directed by the counselor. A non-directive approach to patient decision making is the cornerstone of genetic counseling. It supports patient autonomy, helps assure that patients own their decision, and helps them adapt to painful clinical circumstances. Many patients ask, "What would you do if you were in my situation?" Non-directive counseling refocuses the discussion by identifying factors contributing to the patient's decision making, such as life experiences and personal values and beliefs. The genetic counselor allows the patient to decide whether to pursue or decline prenatal testing and supports this decision.

The patient with positive results from her maternal serum screening for Down syndrome may opt to pursue or decline amniocentesis.

Counselors strive to make clear that any course of action taken by the patient based on the results of prenatal testing will be supported by provision of further information and referral for care, whether the patient's decision is to continue a pregnancy, interrupt a pregnancy, or place the child for adoption. (See Table 2).

GENETIC COUNSELING FOR ULTRASOUND ANOMALIES

Another common indication for referral for prenatal counseling is a second trimester ultrasound which raises the suspicion of a fetal anomaly. A couple may be referred for a targeted, or Level II, ultrasound for confirmation. When a fetal anomaly is confirmed through Level II ultrasound, the counselor provides "crisis counseling," because the anomaly is usually unanticipated and the patient is given unexpected "bad news." A patient's shock, disbelief and intense sadness may interfere with her ability to com-

prehend what is said to her, subsequent to hearing the diagnosis. Counselors review the ultrasound findings, prognosis, and options for further testing, treatment or intervention. For example, in counseling about gastroschisis, the counselor explains what ventral wall defects are and how they arise. The differential diagnosis for gastroschisis includes a ruptured omphalocele, a ventral wall defect involving the umbilical ring usually covered by amnion. Omphalocele has a significant association with fetal aneuploidy and other genetic syndromes. The prognosis of these defects and the need for surgical repair are discussed. Also, because a ruptured omphalocele cannot be uniformly distinguished from gastroschisis via targeted ultrasound, amniocentesis is offered to rule out an underlying chromosome abnormality. If omphalocele is suspected, fetal echocardiography is indicated to detect associated fetal cardiac defects. Clinical options for patients are discussed and, if accepted by the patient, consultation with pediatric surgery is obtained. In addition, patients may want to consult with parents of a child with a similar condition or with local and/or national support organizations.

In the preceding scenario, counselors answer patients' questions and provide emotional support. Validation of parental reactions and feelings by the entire medical team, including sonographers, physicians and genetic counselors, is essential. For some patients, the opportunity to share their feelings in an empathic and supportive environment can help them cope.

FUTURE DIRECTIONS

The accelerating expansion of genetic knowledge has made clinical genetics an important part of the diagnostic and therapeutic agenda in all areas of medicine. DNA-based testing for and treatment of genetic diseases will increasingly become a part of clinical decision making. As the volume of information expands, physicians will come to rely more on interactive databases and genetic counseling services. Genetic counselors are becoming a more widely sought resource for patients, health care providers, and the community.

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Detection and Management of the Intrauterine Growth Restricted Fetus

Stephen R. Carr, MD

Intrauterine growth restriction (IUGR) affects between 4% and 8% of all pregnancies in developed countries, but is found in 50% of stillbirths and 20% of neonatal deaths. Intrauterine growth restriction is defined by rate of growth, a change in fetal size over time, that is significantly less than that predicted. This differs from the term, "small for gestational age," (SGA) which describes differences between observed and expected fetal size. Where SGA can be detected with a single measurement compared to gestational age-specific norms, IUGR can be diagnosed only with calculations from two or more measurements made over time.

Both the growth restricted and small for gestational age fetus have been categorized in two ways - symmetric and asymmetric. Symmetric IUGR is

said to be present when all growth rate measurements are equally smaller than expected; asymmetric IUGR when only the growth of the abdominal circumference is less than expected. Asymmetric IUGR is thought to be the result of impaired placental nutrient delivery to the fetus that occurs relatively later in gestation which also may be characterized by chronic mild fetal hypoxia. The latter condition can be associated with shunting of nutrient flow to the head, forelimbs and heart with resulting disproportionate growth restriction of the trunk. However, even without associated hypoxia, fetal growth restriction based on nutrient deficit will result in

Abbreviations Used:

AC	abdominal circumference
EFW%ile	estimated fetal weight centile
hCG	human chorionic gonadotropin
IUGR	intrauterine growth restriction
MoM	multiple of the median
MSAFP	maternal serum markers alpha-fetoprotein
NST	non-stress tests
S/D	ratio systolic to diastolic ratio
SGA	small for gestational age

reduced fat and glycogen stores that will be more sensitively reflected in reduced fetal abdominal circumference growth. Symmetric IUGR, on the other hand, is thought to occur earlier in gestation and to be produced by heterogenous pathologies including infection of fetus or placenta, ionizing radiation, karyotypic abnormalities, and severe hypoxia and nutrient insufficiency (Table 1)¹

Table 1: Factors thought to be causative or associated with fetal growth restriction

<u>Maternal</u>	<u>Placental</u>
caloric restriction	abruptio placenta, infarction
altitude hypoxia	antiphospholipid antibody syndrome
drugs: tobacco, ethanol, cocaine, heroin, propranolol, cytotoxic chemotherapeutics	infection (see below)
chronic hypozemia from cardiopulmonary diseases	<u>Fetal</u>
hemoglobinopathies	congenital malformations
hypertension	aneuploidy
renal disease	infection (CMV, rubella, TB, syphilis, Toxoplasma)
	multi-fetal pregnancy

Table 2: Growth Velocities of Fetal Body Measurements

Measurement	Growth Velocity
BPD	growth rate=2.59 + 0.127*(MGA) - 0.000447*(MGA) ²
AC	growth rate=11.3 + 0.102*(MGA) - 0.00534*(MGA) ²
FL	growth rate=5.49 - 0.17*(MGA) + 0.00181*(MGA) ²

BPD: biparietal diameter
FL: femur length

AC: abdominal circumference
MGA: mean gestational age

DIAGNOSIS OF IUGR

The diagnosis of IUGR based upon gestational age-specific norms requires knowledge of gestational age. Routine measurements of fundal height at prenatal visits offer a rough guide to fetal growth, but are subject to error due to maternal body habitus, amniotic fluid volume, and variations in measurement technique. The precision (95% confidence limits) of sonographic gestational age estimates based on crown rump length (+5 days), second trimester biparietal diameter (+8-13 days), and third trimester femur length (+20 days) vary significantly. Moreover, the uncertain gestational age of pregnancies used to construct the normative values and interfetal variation both increase the breadth of the distribution of fetal size at a specified gestational age.

Table 3: Sensitivity and Specificity of Fetal Size Measurements for IUGR at Birth							
	AC	BPD	HC:AC	FL:AC	EFW	Any Two	EFW%ile
sensitivity	0.96-1.0	0.24-0.88	.7	0.57-0.63	0.63-0.87	0.69	0.63-0.87
specificity	0.6	0.62-0.94	0.94	0.78-0.83	0.88	0.88	0.88

IUGR can be diagnosed with greater accuracy by measuring growth rate directly. First, rates of increases in fetal dimensions normally remain stable throughout pregnancy so that, independent of gestational age, deviation from the expected value may be used with the same precision (femur length > abdominal circumference > head dimensions). For example, the abdominal circumference (AC) measurement is observed to increase nearly linearly ($AC = -6.93 + (1.0985 \times \text{menstrual age})$, $R^2 = 0.955$) throughout pregnancy at a rate approximating 1.1 cm per week. In cases of asymmetric IUGR mediated by some form of placental insufficiency or reduced uterine blood flow, the fetal abdominal circumference rate of change will show a greater deviation from expected values compared to other fetal growth rates (Table 2).

Even with a reasonable estimate of gestational age, a single observation of fetal dimensions has been estimated to identify fetal growth restriction at birth with sensitivity and specificity estimated at 60-100%. Uncertainty regarding gestational age can be theoretically accounted for by calculating ratios of a growth restriction-sensitive fetal dimension (e.g., AC) to a fetal dimension that is less sensitive to growth disturbances (e.g., femur length). Despite their intuitive appeal, however, the sensitivity and specificity of dimensional ratios for fetal growth restriction diagnosed at birth is not markedly improved over that of fetal dimensions alone, probably because both rely on cross sectional normative data (Table 3). Likewise, combining several ultrasound measurements in order to reduce the effect of measurement error on growth estimation does not improve our ability to detect IUGR (Table 3). Of the single measurements, estimated fetal weight centile

(EFW%ile), that is, the estimated fetal weight compared to the weight expected based on gestational age, gender and singleton vs multiple pregnancy, is probably our best way of detecting IUGR.

A methodical approach to the detection and management of these growth restricted fetuses will decrease the associated morbidity and mortality.



Management of the growth restricted fetus is predicated, in part, on the gestational age of the pregnancy. Impaired growth near term does not present much of a therapeutic dilemma - if growth is inadequate, and there is reasonable certainty that the fetus will do well as a neonate, then delivery is appropriate. This assessment is based in large part on the technical capabilities of the receiving nursery. A more difficult decision presents when inadequate growth is detected remote from term. In this situation, delivery of the fetus may be justified if the perinatal morbidity risk associated with continuing gestation is likely to be higher than that associated with prematurity. How best to make this assessment has been the subject of a great deal of investigation, most of it within the construct of

asymmetric IUGR, with the assumption of relative placental insufficiency.

Extensive placental infarction in animal models produces fetal growth restriction and increased impedance to flow in the umbilical artery. While actual flow measurements cannot be obtained in the human fetus, measurement of umbilical blood flow velocities are relatively simple using spectral Doppler analysis. Because of the angle dependent nature of absolute velocity measurements, a variety of ratios have been proposed as proxies for flow measurements. (Table 4)

These ratios can be measured independent of the angle between the ultrasound beam and the umbilical artery. As long as identifiable Doppler signals can be obtained, the ratios can be calculated. The S/D ratio is the simplest to calculate, and contemporary Doppler-capable ultrasound machines will automatically calculate it once the peak systolic and diastolic velocities are measured. The S/D ratio declines slowly over the course of gestation, and normal ranges are easily referenced. As with most of our armamentarium, Doppler functions poorly as a screening tool in a low-risk population. The positive predictive values and negative predictive values are little better than the more traditional ultrasound measurements and ratios. In a high-risk population, however, there is substantial evidence that use of Doppler assessment will decrease perinatal mortality. A recent meta-analysis³ demonstrated a 38% fall in the odds ratio for perinatal mortal-

Table 4: Ratios for Assessments of Umbilical Arterial Blood Flow	
Resistance Index	(S-D)/S
Pulsatility Index	S-D)/A
S/D ratio	S/D
S: peak systolic velocity	
D: peak diastolic velocity	
A: average of peak systolic and diastolic velocities	

IUGR EVALUATION FLOW DIAGRAM

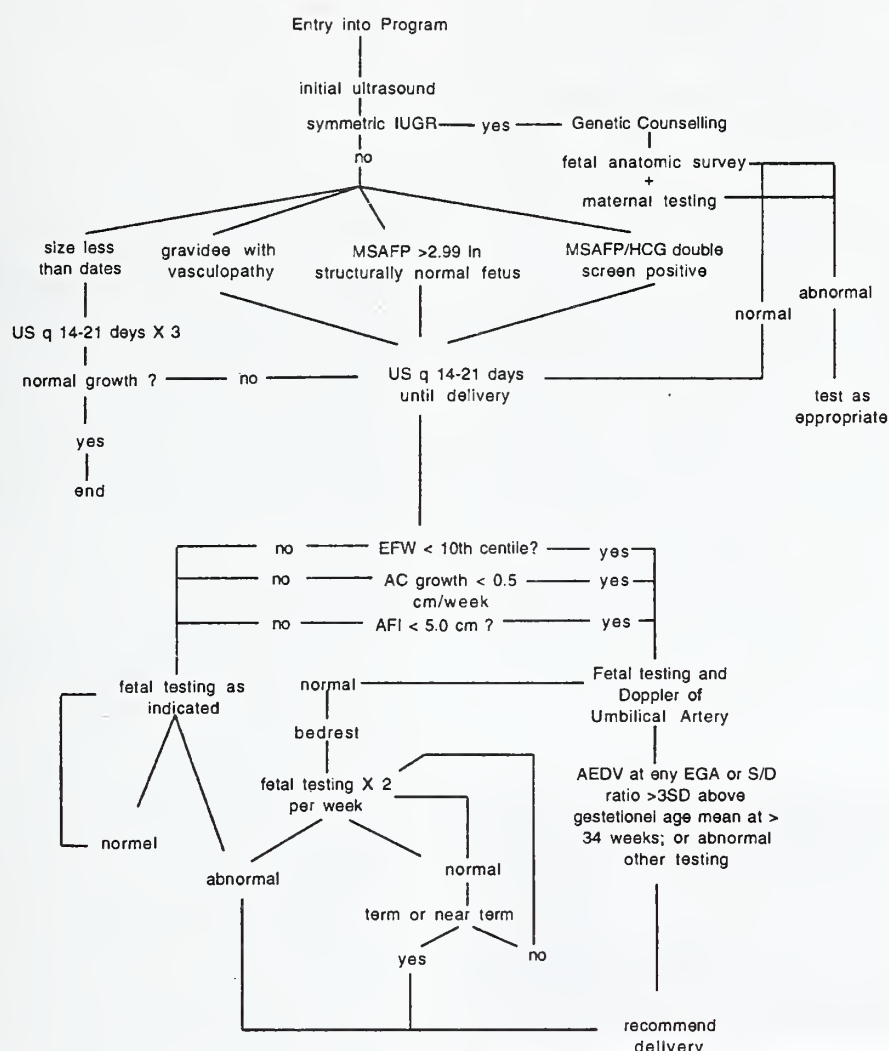


Figure 1.

ity in groups in whom Doppler assessment was used compared to high risk groups in which Doppler assessment was not used. The effect was most apparent in groups at the highest risk - those in whom there was no end-diastolic flow, or in whom there was actual reversal of umbilical arterial flow during diastole.

MANAGEMENT OF INTRAUTERINE GROWTH RESTRICTION

Figure 1 presents a conservative management plan for the evaluation and treatment of potential or actual IUGR. Following diagnosis, the first step is to define the type of growth restriction. If the IUGR is symmetric, investigation of the possibility of chromosomal abnormalities or intrauterine infection is advisable. In the case of chromosomal abnormalities, the expertise of a genetic counselor is invaluable. If intrauterine infection is

suspected, serologic assays for toxoplasmosis, rubella, varicella, cytomegalovirus, plasmodium, and Trypanosoma cruzi should be considered. Targeted ultrasound may help detect effects of intrauterine infection.

There are no available reparative interventions if a fetal infection is present, but antibiotic treatment may prevent further effects of fetal or placental infection. The observed or potential effects may be sufficiently profound that the couple may elect termination.

If asymmetric IUGR may be associated with second trimester maternal serum markers such as alpha-fetoprotein (MSAFP) values of

>3.0 in a structurally normal fetus of the so-called "doublescreen positive" fetus with both MSAFP and hCG >2.0 MoM or may be associated with poor maternal nutrition and weight gain, chronic maternal medical disease such as hypertension or diabetes, or maternal smoking. If no correctable causes are found, then intensive fetal testing is warranted. In this context fetal evaluation consists of serial ultrasound scans to document fetal growth velocity. Intervals of less than 10 days between sonograms are not advisable because of the variability of the measurements; adequate growth may have occurred but may not be detected. Comparison of fetal measurements over time will allow calculation of fetal growth velocities, and comparison to normative values. If the growth velocity is adequate, then it may be that the fetus is constitutionally small. If the fetus is SGA and the growth velocity is below the lower limit of normal, then consideration should be given to delivery. Remote from term, however, the decision to deliver should rely not only on growth velocities, but on balancing the estimated perinatal risks of prematurity with that of a potentially injurious intrauterine environment. This can be addressed, in part, by examination of fetal behavior or with tests that provoke mild reductions in placental perfusion. These studies should include non-stress tests (NST) and fluid volume checks (the so called modified bio-



physical profile), the complete biophysical profile, Doppler velocimetry of the umbilical artery and the contraction stress test.

It has been habit to suggest maternal bed rest, either at home or in the hospital, as a means of increasing uterine perfusion and improving fetal environment to allow improved fetal growth. However, the efficacy of this intervention in routine cases of IUGR has not been established. Other interventions have been attempted with the aim of decreasing the chances of IUGR occurring in women at risk for this disorder. A recent meta-analysis presents data from 13 randomized trials on the use of low dose aspirin in pregnancy that, in aggregate, suggest a significant reduction in IUGR. The odds ratio was

0.8, with 95% confidence limits of 0.72-0.93. The preventative effect is greater at higher doses (100-150 mg/day), but the safety of such doses has not been established. Interestingly, the significant reduction in IUGR was associated with a non-significant reduction in perinatal mortality (odds ratio 0.84; 95% CI 0.66-1.08).⁴

There has been little impact of medical care on the incidence of IUGR. However, its detection and surveillance in utero, the timing of pregnancy termination, and the ability of nurseries to care for these babies have all substantially improved. A methodical approach to the detection and management of these growth restricted fetuses will decrease the associated morbidity and mortality. The

Prenatal Diagnosis Center at Women and Infants Hospital provides complete assessment and surveillance services for gravidas with suspected IUGR. Referring physicians are provided with recommendations regarding diagnostic and management options and patients have access to counseling services from masters-trained genetic counselors. Despite the limited knowledge that medicine brings to the management of these affected pregnancies, we feel that a coherent plan of fetal evaluation, timed delivery and collaboration with neonatologists provides for an optimal outcome.

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Managing AIDS in Pregnancy

Jami A. Star, MD, and Raymond Powrie, MD

AIDS is one of the leading causes of death in women of reproductive age in the United States. Since 1981, when the first case of AIDS in a woman was reported, the gender difference in infection has been narrowing. Sero-prevalence varies geographically, with the highest rates in urban centers. In addition, racial and ethnic minorities, such as Latinas and African Americans, comprise the overwhelming majority of infected individuals despite their limited representation in the population. Worldwide, the prevalence of disease in sub-Saharan Africa and Southeast Asia has taken on epidemic proportions. The tragedy is compounded, because mother to infant transmission accounts for almost all cases of HIV infections among children.

Intravenous drug use was initially responsible for the majority of AIDS cases in women, but recently the pattern of transmission has changed. Since 1993, heterosexual contact has been the primary means of transmission for women,¹ suggesting that all pregnant women are at risk by virtue of their exposure to unprotected sexual intercourse. Additional risk factors include: blood products received between 1977- 1985, history of a sexually transmitted disease (or sexual contact with someone with that history), origin from a region with a high rate of HIV infection (i.e. Africa, Southeast Asia, India, eastern Europe, the Caribbean basin), or involvement with multiple sexual partners.

ANTENATAL TESTING

Many states, including Rhode Island, require that all pregnant women be counseled regarding the option of HIV testing at the beginning of their pregnancy. Screening only those women with reported risk factors will detect, at most, 60% of infected

women.² The use of zidovudine (AZT) has been shown to significantly limit the risk of vertical transmission. Therefore, the law also requires that women who test positive be counseled as to AZT's benefits. However, because of privacy and discrimination, and the impossibility of forcing patients to take AZT, no state has instituted mandatory HIV testing of all pregnant women. Legal requirements to notify the partner of an infected individual vary: this is not mandated in Rhode Island.

Screening must be accompanied by extensive pre- and post- test counseling. Patients must be notified as to the risk of both false positive and negative tests. All tests, positive on preliminary screening, are subjected to more definitive analysis. Conversely, tests may not identify all infected persons especially after recent exposure and infection prior to the development of seropositivity. Patients with high risk of exposure may be retested six months after a negative test result. Counseling should also outline the recommended options for therapy.³

The issue of reproductive choice is the same for all pregnant patients, with or without HIV. At the first prenatal visit, patients are commonly asked whether their pregnancy was planned, and whether it is desired. The option to terminate may be addressed with any patient who does not wish to continue a pregnancy for any reason. Studies have shown that the majority of HIV positive women will not elect to terminate a pregnancy, and several have chosen to reproduce more than once after the diagnosis of HIV infection.⁴

Abbreviations Used:

AIDS	acquired immune deficiency syndrome
AZT	zidovudine
FDA	Food and Drug Administration
HIV	human immunodeficiency virus
PPD	purified protein derivative [tuberculin]
TORCH	toxoplasmosis, cytomegalovirus, rubella and herpes

EFFECT OF PREGNANCY ON CLINICAL COURSE OF HIV INFECTION AND AIDS

One question considered early in the HIV epidemic was whether pregnancy had any adverse effects on the course of HIV disease. While several clinical manifestations of the infection are specific to women, the overall course of infection in men and women who receive similar care is comparable.¹ However, because pregnancy is often considered a state of relative immunosuppression, there was initial concern that this condition would accelerate disease progression. It is now known that pregnancy is associated with a drop in CD4 counts in both HIV positive and negative women, with a nadir reached approximately two months prior to delivery. Studies are limited regarding long- term survival after pregnancy, but there appears to be no acceleration of disease either during or after pregnancy in HIV positive women. Likewise, the incidence of opportunistic infections has not been found to increase during pregnancy. Measurement of CD4 counts, as well as plasma viral load, continues to be the primary means of disease assessment during pregnancy.⁵

Management of pregnancy in HIV positive women includes "routine" prenatal care, as well as careful observation for any evidence of disease progression. This is best accomplished

with a multi-disciplinary approach, involving obstetricians, internists and ancillary providers (e.g., nutritionists and social workers). Dyspnea, weight loss, fatigue and sweats - common in normal pregnancy - should not be "written off" in patients with this disease. A thorough physical exam at each visit is advised, with adjunctive laboratory testing as indicated. Additional clinical assessment might include: serologic testing for hepatitis C (in addition to routine testing for hepatitis B), and for TORCH infections (toxoplasmosis, cytomegalovirus, rubella and herpes) which may have both maternal and fetal implications, baseline liver function tests, aggressive follow-up of abnormalities on the Pap smear (cervical cancer has recently become a disease-defining diagnosis), evaluation of anemia and thrombocytopenia, and PPD testing for tuberculosis with more definitive skin testing if anergic.

EFFECT OF HIV INFECTION AND AIDS ON PREGNANCY

In the United States, HIV positive women do not have measurably different obstetrical outcomes than age-matched women of a similar socioeconomic status. Despite initial findings to the contrary, repeated studies show no increase in preterm delivery, premature rupture of membranes, intrauterine growth restriction, fetal infection or miscarriage. There is an increase in the presence of sexually transmitted diseases, however.⁶ The absence of adverse effects on pregnancy may be related to the fact that most HIV positive pregnant women studied in this country have not progressed to AIDS. By contrast, in Kenya, where HIV infected women may have greater burden of AIDS-independent comorbidity and may be at a more advanced state of disease, and where different viral serotypes may be prevalent, clinicians have reported decreased birth weight, prematurity and increased risk of postpartum endometritis.⁷

OPTIMAL TREATMENT OF THE HIV INFECTED WOMAN DURING PREGNANCY

While the optimal treatment has not been determined, recommendations include the use of AZT. While transmission rates were found to be approximately 30% worldwide in the absence of treatment, the AIDS Clinical Trials Group Protocol 076 documented a decrease in the transmission rate to 8% in conjunction with AZT therapy.⁸ This randomized placebo-controlled trial was conducted in pregnant women with CD4 counts greater than 200/cubic millimeter and absence of prior exposure to anti-retroviral therapy. Women were treated antepartum (100 mg zidovudine five times a day) and during labor; infants were treated for six weeks postnatally. Side effects were minimal in both mothers and infants. The dramatic findings spurred premature termination of the trial, with subsequent recommendations to treat all HIV positive pregnant women with AZT. However, this trial did not provide information about the minimal dose or duration of zidovudine, nor its optimal timing.

ETHICAL DIMENSIONS TO MULTI-DRUG THERAPY IN PREGNANCY

Newer treatment options in HIV positive women in pregnancy have provoked several clinical uncertainties with ethical dimensions. The most significant concern is a lack of data on the effects of anti-retroviral agents on the fetus. At present, in the non-pregnant individual, AZT monotherapy is not generally used due to an increased risk of viral resistance with this regimen. Treatment protocols usually combine drugs, including nucleoside reverse transcriptase inhibitors (such as didanosine and lamivudine, in addition to zidovudine), protease inhibitors (such as indinavir, saquinavir and ritonavir) and non-nucleoside reverse transcriptase inhibitors (such as nevirapine).⁹ Only zidovudine has been studied extensively in pregnancy.

Placental transfer has been documented for several of these medications. Animal studies, primarily in rats

and rabbits, suggest limited teratogenicity. Most of these drugs have been labeled as FDA category B or C. Category B suggests the absence of risk for humans based on animal and/or human studies. For example, many drugs administered during pregnancy, including most antibiotics, are in this category. By contrast, category C implies that human and/or animal studies have either shown risk or data are unavailable. The use of drugs in this category is warranted when potential benefit appears to outweigh risk.¹⁰

Avoidance of microbial drug resistance may justify use of anti-retroviral agents other than AZT in pregnant women with HIV or AIDS. Zidovudine monotherapy, limited to the duration of pregnancy, may encourage the development of resistant viral strains and compromise later treatment and/or survival. Although studies are limited, most of the anti-retroviral drugs have not been shown to have significant teratogenic effects in animals. Consequently, the traditional caution and extensive testing which is generally employed for medication use in pregnancy may not be applicable in the face of the significant morbidity and mortality risks in both mothers and infants infected with HIV. Certainly, the safety of zidovudine was not firmly established when its use in pregnancy was initiated. Given the lack of definitive data, pregnant patients with HIV must be counseled about the potential risks and benefits of the treatment options available and therapeutic decisions made based on informed consent.

OPPORTUNISTIC INFECTION PROPHYLAXIS

Prophylaxis and treatment for opportunistic infection is largely the same for the pregnant and the nonpregnant individual. Trimethoprim/sulfamethoxazole remains the first line agent for prophylaxis of *Pneumocystis carinii* infections. This medication may theoretically increase risk of neonatal encephalopathy due to displacement of bilirubin from albumin, but there have been no reported cases following in utero exposure. Therefore, the drug

should be considered safe for use in pregnancy for this indication. Pentamidine is an acceptable alternative in the presence of other contraindications such as maternal allergy.¹¹

OTHER PREVENTION MEASURES TO REDUCE VERTICAL TRANSMISSION

Despite the use of various therapies, it is clear that in utero transmission of the virus does occur and has been documented as early as 8 weeks gestation age in abortuses¹² - suggesting that vertical transmission is unlikely to be completely eliminated. Maternal risk factors for increased transmission include viral load (evidenced by high plasma viral RNA or decreased CD4 counts), degree of maternal P24 antigenemia, presence of symptomatic infection, and concurrent sexually transmitted disease.¹³ Around the time of delivery, additional factors may influence transmission if it has not already occurred. Evidence suggests that rupture of membranes for greater than 4 hours prior to delivery may increase the risk of perinatal infection.¹⁴ Invasive procedures, such as fetal heart rate monitoring with a scalp electrode, fetal blood sampling through a scalp incision, and operative vaginal delivery with forceps or vacuum are relatively contraindicated due to a theoretical risk of transmission through a broken skin barrier.

The mode of delivery (vaginal birth versus cesarean section) has not been shown clearly to affect transmission. The European Collaborative Study in 1991 documented a slightly decreased risk of transmission with cesarean section which was not statistically significant. This question is currently under further study.¹⁵ Based on these data, cesarean section is presently performed only for usual obstetric indications, because the efficacy of abdominal delivery in preventing transmission has not been confirmed but remains a risk to the mother. The effect of delivery route on risk of transmission has not been studied in the setting of aggressive anti-retroviral treatment, including AZT.

Delivery of twins offers some pos-

sible insight. Significantly higher risk of infection in the first-born has been observed independent of route of delivery. However, the disparity was greater in those born vaginally, with almost a three-fold difference¹⁶ - suggesting increased risk based on exposure to an infected birth canal. Studies are underway in Malawi on antiseptic lavage of the vagina prior to delivery, also suggesting that liberal washing of the neonate, born by either route, may decrease viral load and provide an effective universal means of reducing vertical transmission.

HIV is an important cause of morbidity and mortality in women of child-bearing age.

Pregnancy does not appear to have any adverse effects on the course of HIV disease, nor does the disease predispose to poor obstetrical outcomes.



In the US, breast-feeding is contraindicated in HIV positive women. Virus is present in breast milk and the risk of transmission from breast-feeding alone is approximately 7 to 22%. Women with a history of high-risk behaviors may also be counseled against breast-feeding in the event that they may not have developed seropositivity

to a recent infection. In developing countries, where acceptable alternatives to breast milk may not be available, bottle feeding may be associated with a higher infant mortality.¹³

POST-PARTUM MANAGEMENT

The postpartum period is an opportunity for multiple preventive health interventions. Following delivery, HIV positive mothers must be observed carefully for signs or symptoms of infection, as there may be an increased risk of postpartum endometritis. Infant bonding should be encouraged, although contact with maternal body fluids should be avoided. HIV positive women must be advised as to their increased risk of cervical dysplasia or cancer and should be encouraged to see their physicians at least twice yearly for Pap smears. Patients also should be counseled on options for contraception. Arrangements for medical follow-up must be made prior to discharge. Finally, many patients with this diagnosis are at risk for depression and social isolation. Patients should be alerted to support services in the community.

HIV is an important cause of morbidity and mortality in women of child-bearing age. Pregnancy does not appear to have any adverse effects on the course of HIV disease, nor does the disease predispose to poor obstetrical outcomes. AZT use in pregnancy dramatically decreases maternal-fetal transmission of HIV. The authors believe that women should be given the option of multi-drug therapy during pregnancy, in the hope of decreasing maternal morbidity and perhaps further decreasing vertical transmission.

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Deep Venous Thrombosis and Pulmonary Embolism in Pregnancy

Raymond Powrie, MD, Jami A. Star, MD, and Karen Rosene-Montella, MD

Pregnant women are known to be at an increased risk for thromboembolic disease. Pulmonary embolism is the major, non-obstetric cause of maternal mortality in the United States and Canada. Risk factors for thromboembolic disease in pregnancy include immobilization, obesity, smoking, surgery (including cesarean section), and presence of an inherited or acquired hypercoagulable state. Two physiologic changes in pregnancy that contribute to the predisposition to venous thrombosis are (1) "stasis" of blood in the large vessels of the pelvis and legs due to proximal obstruction from the gravid uterus and increased venous compliance and (2) increased levels of all of the coagulation factors involved in clot formation (except Factors XI and XIII) and decreased fibrinolysis.¹

The effect of the pregnancy-induced increase of procoagulant activity is further amplified by a reduction in levels of some of the normally occurring serum anti-thrombotic proteins during pregnancy. A decrease in protein S that occurs in all pregnant women is the most well known of these changes.

DIAGNOSIS OF DEEP VENOUS THROMBOSIS

The risk of pulmonary embolism and deep venous thrombosis, though higher in pregnancy, is not affected by the duration of pregnancy. The incidence for thromboembolism peaks in the first 48 hours after delivery and continues to be increased for up to six to twelve weeks postpartum. Ninety percent of deep venous thromboses in pregnancy occur on the left side. The reason is not well understood, but may relate to the position of the uterus with respect to the left iliac vein, which enters the vena cava at a more acute angle and may be compressed by the iliac artery.²

Typically, deep venous thrombosis in pregnancy presents with unilateral leg edema, pain and tenderness. However, the accuracy of diagnosis by history and physical exam is notoriously unreliable. Compression ultrasound of the lower limbs, impedance plethysmography, and contrast venography can be safely done during pregnancy with reliable results. However, a significant proportion of deep venous thromboses in pregnancy occur in the pelvic veins and may remain undetected by compression ultrasound or even lower limb venogram. In those cases where a high index of suspicion is met with a negative lower limb compression ultrasound, a skilled sonographer can examine the iliac and femoral veins with considerable accuracy. In the rare situation, where some doubt remains regarding the presence of pelvic clot, we have found magnetic resonance venography to be very helpful.

DIAGNOSIS OF PULMONARY EMBOLISM

Pulmonary embolism in pregnancy may have a more subtle presentation than in the general medical population. Thus, a consideration of this diagnosis is warranted even in pregnant patients with mild and non-specific symptoms. A review of cases of pulmonary embolism in our own institution found that fewer than half of patients with documented pulmonary embolism had widened Arterial-alveolar gradients (>20 mmHg), tachycardia (>100 bpm), or characteristic pleuritic chest pain.³ Also, fewer than half had EKG or chest x-ray findings. The most common presenting feature was dyspnea. Since dyspneic symptoms present commonly in the uncomplicated pregnancy, the decision about which patient to investigate for pulmonary em-

Abbreviations Used:

APL ab	antiphospholipid antibodies
DVT	deep venous thrombosis
EKG	electrocardiogram
IgG	immunoglobulin G
IgM	immunoglobulin M
PCR	polymerase chain reaction
PTT	partial thromboplastin time

bolism can be difficult.

When a reasonable suspicion of pulmonary embolism arises with respect to a pregnant patient, the minor fetal risks posed by radiation and osmotically active contrast media are far outweighed by the benefits of confirming or excluding this common and life-threatening diagnosis. Chest x-rays, ventilation perfusion scans and pulmonary angiograms can be done safely during pregnancy, with a dose of radiation that is well below the generally accepted limits of fetal radiation exposure. The ventilation perfusion scan is often diagnostic in young, healthy individuals with no pre-existing lung disease. A normal lung scan effectively rules out a pulmonary embolism, while a high probability scan effectively confirms the diagnosis. With a "low" or "intermediate probability" scan result, a pulmonary angiogram is often necessary to diagnose or exclude pulmonary embolism. The life-threatening nature of pulmonary embolism and the lifelong clinical implications of the diagnosis of thromboembolic disease in a young person almost always warrant a definitive answer even if pulmonary angiography is required.

TREATMENT OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM

Treatment of acute deep venous thrombosis and pulmonary embolism in pregnancy is done initially with intravenous heparin (just as for the non-

pregnant patient). Heparin is a large molecule which does not cross the placenta and therefore has no effect upon the fetus. The risks of heparin are maternal and include hemorrhage, osteoporosis, and thrombocytopenia, all of which are relatively rare and outweighed by the benefits of heparin therapy. After five to seven days of intravenous heparin, the patient with DVT and/or pulmonary embolism is discharged on twice daily subcutaneous injections. Full anticoagulation with subcutaneous heparin is monitored with the goal of achieving a mid-interval (6 hours after a q 12h dosing), PTT of 60-80 seconds. To achieve this level of anticoagulation, we prescribe half the total number of units of intravenous heparin required over a 24-hour period for anticoagulation to be given subcutaneously every 12 hours. Duration of treatment is controversial but should be at least 3 months. If the patient is still pregnant after three months of therapeutic heparin have been administered, many people would continue full anticoagulation therapy while others would switch to a prophylactic dose.⁴

Although the nonpregnant patient with thromboembolic disease is managed chronically on warfarin, it is contraindicated in pregnancy. Warfarin (Coumadin) readily crosses the placenta and acts as a teratogen in the first trimester. Later in pregnancy, warfarin is associated with an increased incidence of cerebral malformations presumably related to fetal cerebral hemorrhage. In the rare situation when an acute pulmonary embolism occurs in a pregnant patient who cannot undergo systemic anticoagulation with heparin, inferior vena cava filters can be placed safely.

The utility of low molecular weight heparin in pregnancy is yet to be defined. Like unfractionated heparin, it does not appear to cross the placenta. Because of its ease of use and fetal safety, it would appear a reasonable alternative to unfractionated heparin therapy during pregnancy. However, its expense and the lack of high-dose vials in the United States limit its use in pregnancy.

Pulmonary embolism in pregnancy may have a more subtle presentation than in the general medical population. Thus, a consideration of this diagnosis is warranted even in pregnant patients with mild and non-specific symptoms.



PROPHYLAXIS

Because pregnancy is associated with an increased risk of DVT and pulmonary embolism, many individuals believe that women who have had a previous deep venous thrombosis or pulmonary embolism, regardless of its etiology, require prophylactic heparin during their pregnancy and for 6 weeks postpartum. The risk of thrombosis in a pregnant women with a previous thrombotic event is not known, nor is the efficacy of prophylactic heparin to prevent recurrent thrombosis. We recommend use of heparin at 5000 units subcutaneously (SC) in the first trimester, 7500 units SC q 12h in the second trimester, and 10,000 units SC every 12 hours in the third trimester as reasonable prophylactic regimen. The increased doses in the second and third trimester are based on the assumption that the same dose may be less efficacious in the latter two trimesters since lower doses result in often undetectable heparin levels at later gestation. When the patient goes into labor, the heparin is stopped and resumed 12-24 hours postpartum. In our experience heparin reversal is not required in the context of heparin prophylaxis at the time of labor onset. The cessation of uterine bleeding at parturition is not compromised by heparin. However, assiduous repair of lacerations and incisions is required for he-

mostasis in this circumstance.

Because the increased risk of thrombosis continues for at least 6 weeks postpartum, we either continue heparin treatment at a dose of 5000 units subcutaneously every twelve hours, or give the patient the option of using warfarin for 6 weeks after delivery. If the patient opts for warfarin, we try to keep the INR (the test to ensure the dose of warfarin is appropriate) in the low therapeutic range (therapeutic range is 2-3). Both warfarin and heparin are considered to be compatible with breast-feeding, though some may choose to test the nursing infant's prothrombin time after several days of maternal warfarin therapy.

Primary coagulation defects that predispose to thrombosis include the inherited defects such as protein S deficiency, protein C deficiency, resistance to activated protein C (also known as Factor V Leiden mutation) and antithrombin III deficiency and acquired abnormalities such as the antiphospholipid antibody syndromes (antiphospholipid antibody, anticardiolipin antibody, and the lupus-like inhibitor).⁵ Individuals who have an unexplained thrombotic event are now routinely tested for these abnormalities. Although the majority of thromboembolic events in pregnancy will have no clear underlying cause, women with either inherited or acquired hypercoagulable defects may present with thrombosis for the first time during pregnancy. In addition to their association with thromboembolic disease, many thrombogenic coagulation defects appear to be associated with fetal loss, intrauterine growth restriction, and pre-eclampsia, all of which are associated with placental thrombosis.

For each thrombogenic coagulation defect, Table 1 summarizes: (1) the recommended diagnostic test and (2) the effect of pregnancy, heparin therapy and the presence of coexistent thrombosis on each test's function. Only the protein S assay is normally decreased in pregnancy. Resistance to activated protein C is a relatively newly recognized inherited disorder that appears to be responsible for a large propor-

Table I. Inherited and Acquired Tendencies to Coagulation and How to Test for Them in Pregnancy

	Test	Effect of pregnancy on assay	Meaningful in the setting of acute thrombotic event?	Meaningful in the setting of heparin therapy?
protein C deficiency	functional protein C assay	none	no	yes
protein S deficiency	functional protein S assay	decreases levels	no	yes
antithrombin 3 deficiency	antithrombin III assay	none	no	no
factor V Leiden mutation (70%-90% of R-APC)	PCR for factor V Leiden mutation	none	yes	yes
functional resistance to activated protein C	functional assay for R-APC	increases resistance to APC	yes	no
antiphospholipid antibodies	anticardiolipin and antiphospholipid antibodies (IgM and IgG)	none	yes	yes
Lupus like inhibitor	PTT, mixing study, Platelet neutralization procedures (PNP), Russel viper venom (RVV) test and TT	none	yes	no

tion of thromboembolic disorders. Most cases of resistance to activated protein C are associated with a mutation of Factor V (Factor V Leiden mutation), which can be detected with the polymerase chain reaction (PCR). We recommend the PCR test rather than the PTT-based assay be used during pregnancy because the results of the former are not be affected by pregnancy.

The acquired thrombogenic defects are caused by antibodies to phospholipid. They work by interfering with the body's normal mechanisms to impede intravascular clot formation. One of these, the lupus-like inhibitor, causes prolongation of the aPTT in vitro, despite the fact that it predisposes to thrombosis in vivo. Antiphospholipid antibodies (APL Ab) are ordered by that name and both IgM and IgG should be requested. The main two antiphospholipid antibodies identified are antiphosphatidyl serine and anticardiolipin antibodies. Higher titers of these antibodies appear to be associated with a more significant risk of thrombosis than lower titers. Also, IgG appears to carry more risk than

IgM. The lupus-like inhibitor represents a group of disorders that can be identified by the Russell Viper venom and associated tests.

Protein C, protein S, and antithrombin III deficiencies cannot be reliably tested for in the setting of an acute thrombotic event. Antithrombin III cannot be tested for while on heparin. The PCR test for resistance to activated protein C (R-APC) and APL Ab testing can be done meaningfully in the setting of heparin therapy and/or the acute thrombotic event. The Russell Viper Venom Test is accurate in the setting of the acute event but not during heparin therapy.

In summary, deep venous thrombosis and pulmonary embolism occur with increased frequency throughout pregnancy and the puerperium due to increased venous stasis and changes in coagulation factors. The presentation and investigation for these disorders in pregnant women are much the same as in the nonpregnant population, but pregnant women may present with more subtle findings than the older medical population. Heparin is the treatment of choice for DVT and pul-

monary embolism during pregnancy. Warfarin is contraindicated in pregnancy because of its adverse fetal effects. When an unexplained thrombosis occurs in pregnancy, an underlying thrombogenic coagulation defect should be considered. However, many of these investigations may need to be deferred until after treatment has been completed, since test results may be altered by pregnancy and are not always interpretable in the setting of heparin therapy or acute thrombosis.

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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Esophageal Perforation from Maloney Dilator Following Esophageal Biopsy

Meenakshi Aggarwal, MD, Philip B. Vaidyan, MD, and Aijaz Ahmed, MD

The esophageal mucosa may provide critical wall strength and help prevent esophageal perforation.¹ Perforations of ulcerated or otherwise weakened esophageal wall have been described after esophageal biopsies;² however, they are extremely uncommon. We report a case of Maloney dilator induced perforation following esophageal biopsy.

A 77 year old woman underwent esophagogastroduodenoscopy to evaluate a 4-month history of dysphagia. The procedure revealed a small paraesophageal hernia and a stricture at the esophagogastric junction. Two forceps biopsies were taken from the esophagus just proximal to the stricture. The stricture was then dilated using a short taper 44F Maloney-type esophageal dilator; however, resistance was met with a 48F Maloney dilator. No further attempts were made to dilate the stricture. Post-dilation re-endoscopy was not performed. The patient remained asymptomatic initially, but three hours later developed sharp substernal chest pain radiating to the back and worse with inspiration. A chest roentgenogram and gastrografin swallow were indicative of esophageal perforation. An emergent surgery was performed with drainage of the left pleural space and repair of the esophageal rupture. The perforation was located proximal to the stricture and approximated the site of the esophageal biopsy. The patient had an uncomplicated post-operative course.

Four major types of injuries can cause esophageal perforation: bursting, shearing, weakening and piercing.³ We suspect esophageal wall weakening secondary to the biopsy predisposed the esophagus to the Maloney dilator induced piercing-type injury and perforation. Other factors that may have increased the risk of perforation in our patient were presence of esophageal stricture, hiatal hernia and adhesions from multiple abdominal surgeries.³ The incidence of perforations related to conventional dilators varies from 0.09% (Maloney-Hurst dilators) to as high as 2.2% (Celestin dilator); 0.4% for bougienage and 0.6% for metal-olive dilators.^{4,5} In 1991, Pilling-Weck (Washington, Penn.) replaced the traditional long taper Maloney-type esophageal dilators with much shorter distal taper dilators in order to minimize retroversion.⁶ The short taper provided

more distal rigidity and greater directly applied pressure. Thus, the short taper Maloney dilator may have a better pathfinding capability, but this modification may result in a higher rate of esophageal perforation. There may be increased incidence of retroversion with long taper, softer tip Maloney, but it probably has a lower rate of serious complications.⁷ The esophageal perforation caused by Maloney-type dilator is described in the literature as a mild sense of resistance felt during the dilation.⁶ This 'sense of resistance' is usually considered not significant by the endoscopist unless accompanied by other symptoms.⁶ In our case the resistance felt with the 48F dilator was considered not significant, but in actuality an esophageal perforation had probably occurred. Since the most critical factor in the management of esophageal perforation is the time period between injury and therapy,^{8,9} we recommend that endoscopy be routinely repeated after dilation to assess the effects of the procedure.⁶ Biopsy alone can result in esophageal perforation; however, histologic studies of the sample recovered by biopsy under these circumstances usually reveals mediastinal or lung tissue.² In our patient, the histology of the biopsied tissue showed mucosal and submucosal esophageal tissue with chronic inflammatory changes. Thus, the chance that biopsy resulted in esophageal perforation in our patient is less likely. We conclude: esophageal biopsy preceding Maloney dilation is a probable risk factor for dilator induced perforation of the esophagus.

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**Rhode Island
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Edward Westrick, MD, MS

Health Care Quality Improvement in Rhode Island: A Methodology

Rhode Island Quality Partners participates in a variety of projects. Let me take this opportunity to share our project methodology with you. Again, I invite other contributors to this column on health care quality improvement in Rhode Island.

Topic ideas can come from a variety of sources: directly from HCFA, other Peer Review Organizations (PROs), providers, and the literature. The national Cooperative Cardiovascular Project (CCP) was HCFA-directed as is some of our work in Diabetes Mellitus and preventive health services. Our pneumonia project originated from the Connecticut Peer Review Organization. Our Congestive Heart Failure (CHF) project was home grown, in collaboration with Lifespan and Harvard Pilgrim Health Plan.

We cannot select all topic ideas, however good they might be, for actual projects. We prioritize topic selection according to certain criteria: the importance of the problem, the existing evidence base, the existence of practice guidelines, identified opportunities for improvement, the potential for collaboration, and representation of provider settings.

Considerations of importance include the volume, costs, risks, and consequences of the problem. We are working on Diabetes Mellitus because it is a common chronic diseases with preventable, severe, long-term complications. We are working on community acquired pneumonia be-

Abbreviations Used:

ACC	American College of Cardiology
ACE	angiotensin converting enzyme
AHA	American Heart Association
AHCPR	Agency for Health Care Policy and Research
CCP	Cooperative Cardiovascular Project
CHF	congestive heart failure
HCFA	Health Care Financing Administration
HCQIP	Health Care Quality Improvement Program
PRO	Peer Review Organization

cause it is a common reason for hospitalization with a high mortality rate, especially among the elderly.

We look to the existing evidence base to decide whether the opportunity for improvement is supported by strong clinical evidence rather than a matter of opinion. The best evidence is based upon multiple randomized controlled clinical trials. Sometimes we do rely upon the consensus of expert panels. In the secondary prevention of acute myocardial infarction, beta blocker use is supported by the highest level of evidence. In community-acquired pneumonia it is prudent to deliver antibiotics quickly but the evidence support-

ing this practice is merely correlational.

We look for existing practice guidelines and the acceptance of these guidelines in the provider community. We do not look to develop guidelines *de novo* but we may tailor existing guidelines for local use. In acute myocardial infarction we adopted the ACC/AHA guidelines. In diabetes we adopted the guidelines of the American Diabetes Association. In CHF we adopted the guidelines of the Agency for Health Care Policy and Research (AHCPR).

There should be an established, documented opportunity for improvement. This should demonstrate a significant gap between what is best practice and what is commonly practiced. This documentation can come from national studies, surveillance of claims, the primary literature, or collaborating providers. In CHF we know that ACE inhibitors prolong life but their use in ideal candidates falls between 25% and 75%, depending upon the setting. In either case there is considerable room for improvement.

RIQP evaluates candidate projects for the potential for collaboration. We cannot improve quality ourselves. We must work with collaborators. Since collaboration with the PRO is now a voluntary process we must select projects that providers find useful. We also look for the potential to work with external partners. These are like RIQP, not providers themselves, but organizations with common goals, interested in working with us to improve quality. Some of our external partners include the RI Department of Health, Brown University, the University of Rhode Island, the American Heart Association Rhode Island Affiliate and the Diabetes Foundation of Rhode Island (formerly the RI Affiliate of the American Diabetes Association).

We look to the existing evidence base to decide whether the opportunity for improvement is supported by strong clinical evidence rather than a matter of opinion.



We look to represent the various provider settings in our portfolio of projects. In the hospital setting we have projects on acute myocardial infarction, community-acquired pneumonia, and stroke prevention. In the managed care setting we have projects in diabetes mellitus, stroke prevention, and congestive heart failure. In the long term care setting we are developing a project on the prevention and treatment of pressure ulcers. In the near future we hope to offer projects for physician groups and the home care setting.

Once a project has been selected we recruit collaborators by inviting them to participate. Again, participation is voluntary. We have had 100% collaboration on some of our projects: acute myocardial infarction, community acquired pneumonia, and stroke prevention in the ambulatory setting.

Following recruitment we often form a project panel to review literature, identify areas of consensus, adapt guidelines for local use, and design the project. In mammography we have assembled a local steering committee to help us with

a series of projects in breast cancer early detection over the next few years.

In a future edition of this column, I shall address project design, data collection, data analysis, interventions, and evaluation

Please feel free to contact me about any of RIQP's projects: phone (401) 528-3250, fax (401) 528-3210, or email ripro.ewestric@sdps.org.

Edward Westrick, MD, MS, is the Principal Clinical Coordinator of Rhode Island Quality Partners. He is a member of the clinical faculty of Brown University School of Medicine and the Active Medical Staff of Roger Williams Medical Center. He is currently a PhD candidate at the University of Rhode Island studying Pharmacoepidemiology and Pharmacoeconomics.





Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Low Birth Weight Births Delivered at the Regional Perinatal Center

Samara I. Viner-Brown, MS, and William H. Hollinshead, MD, MPH

There are eight hospitals which provide obstetrical services in Rhode Island, including Women and Infants Hospital, our regional perinatal center. As the regional perinatal center, Women and Infants Hospital provides advanced obstetrical and neonatal care for the most challenging pregnancies and the sickest newborns.

Between 1992 and 1997, the total number of babies born in Rhode Island decreased 13%, but there was a 4% increase in those weighing less than 2500 grams. The great majority of the babies born with low birth weights were delivered at the regional perinatal center, and the state's low infant mortality rates indicate that our regional perinatal strategy is effective.

Methods

Data on births in Rhode Island were obtained from the birth certificate database compiled by the state Office of Vital Records. Only births occurring at Rhode Island hospitals were included in this study. Births occurring to

Rhode Island residents at out-of-state facilities were excluded (about 380 per year), as were births occurring in non-hospital settings.

Results

In 1992, 15,161 births occurred at Rhode Island hospitals. By 1997, this number dropped to 13,137 births, a 13.3% decrease. The number of births occurring at the regional perinatal center during this time declined more slowly, from 9,214 in 1992 to 8,669 in 1997.

The number of babies born in Rhode Island with low birth weights (less than 2500 grams) has actually increased over the past five years, from 1,009 (6.6% of all births) in 1992, to an estimated total of 1,052 (8.0%) in 1997. Of the 1,052 babies born at low birth weights in 1997, 869 (82.6%) were born at the regional perinatal center, up from 778 (77.1%) of the low birth weight births in 1992. (Figure 1)

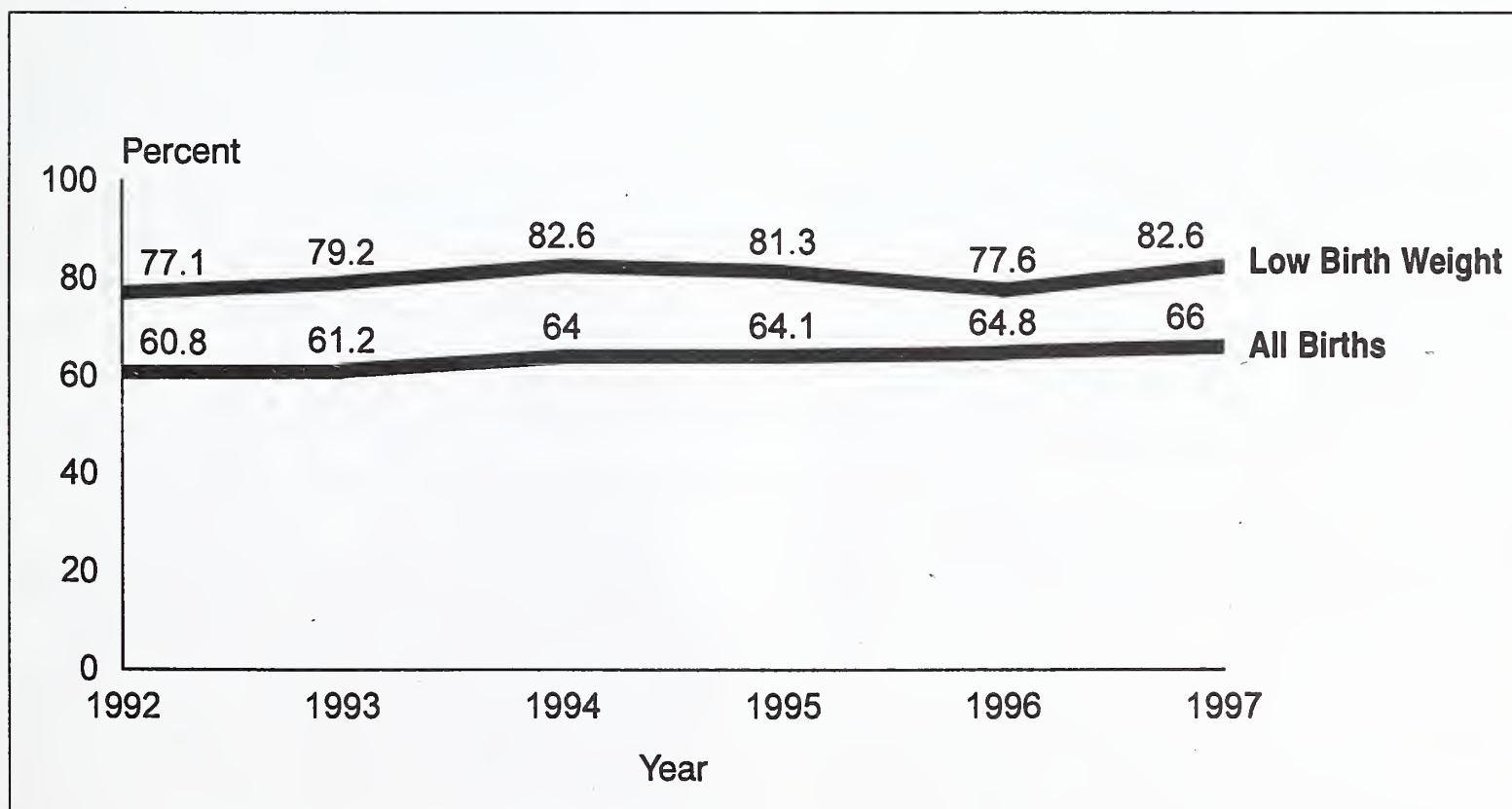


Figure 1: Proportion of Births Occurring at Women and Infants Hospital, Rhode Island Occurrence Births, 1992-1997.

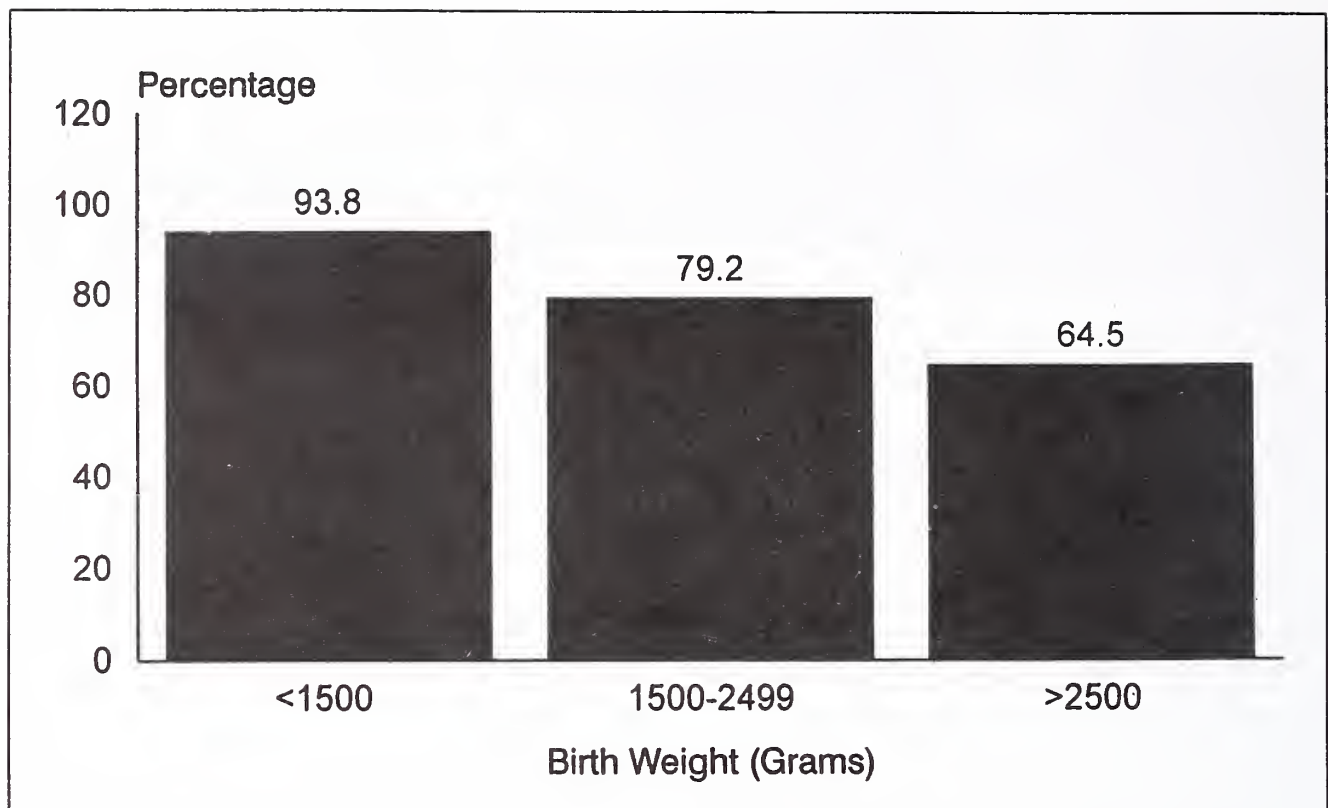


Figure 2: Proportion of all Rhode Island Births Occuring at Women and Infants Hospital by Birth Weight, 1997.

There was a greater percentage increase in the number of babies born at very low birth weights, defined as infants weighing less than 1500 grams. Between 1992 and 1997, the number rose from 221 very low birth weight infants to 243 statewide, a 9.9% increase. In 1997, almost all of Rhode Island's very low birth weight infants, 228 of 243 (93.8%), were delivered at the regional perinatal center. (Figure 2) This proportion has increased since 1992, when 88.2% of the very low birth weight infants were delivered at the regional perinatal center.

Discussion

Although births in Rhode Island have declined, the number of infants born at low birth weights and very low birth weights have increased. The increase in very high risk infants is a prevention challenge, reflecting both old and new threats to infant outcomes. The large and growing majority of these high risk infants are born at Women and Infants Hospital, where there are specialized facilities for their best management, indicating excellent identification and referral of high-risk pregnancies to the regional perinatal center for delivery. Improving state infant mortality rates are evidence that our regional perinatal strategy is succeeding in the face of these challenges and a rapidly changing health care scene.

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Tobacco Use Prevention in Pediatric Primary Care Settings

Alessandra Kazura, MD, and Michael Goldstein, MD

EARLY TOBACCO USE

Tobacco use among youth is increasing at an alarming rate. Between 1991 and 1995, the 30-day point prevalence of cigarette smoking increased from 14% to 19% for 8th graders. Peak ages for first time use of cigarettes are 11 and 12 years, with as many as 29% of 8th graders reporting first use by the end of 6th grade and 9.3% reporting first use by 4th grade.¹ The peak age for daily use is variable, ranging from 13 to 16, with strong cohort effects.¹ Twenty percent of 8th graders reported trying smokeless tobacco and the average age of initial smokeless tobacco use may be as early as ten years. On average, the progression from initiation of smoking to regular use takes two to three years, with considerable individual differences.² Early use of nicotine predicts subsequent heavy smoking rates and increased difficulty in successful quit efforts during adult years.³ 53% of high school seniors who smoke one half pack per day or more report unsuccessful quit efforts,¹ and 75% of daily smokers in high school who are followed longitudinally are still smoking daily seven to nine years later. Breslau and Peterson recently reported that, in a sample of adults between the ages of 21 and 33, the likelihood of cessation for those who had ever smoked daily for one month or more was significantly higher in smokers who had initiated smoking after age 13.⁴ The hazard ratio for quitting associated with smoking initiation at ages 14 to 16 was 1.6 and with initiation at or after 17 was 2.0, compared with initiation at or before age 13. Moreover, youth who do not start smoking by age 18 are unlikely to become adult smokers.² These findings suggest delaying smoking onset until after age 13 may significantly reduce the prevalence of adult smoking.

THE CONSEQUENCES

The harmful effects of tobacco are directly related to duration and intensity of use, both of which are related to early onset of smoking.² The gravest and most commonly known health burdens, such as cancer, predominate in adult age groups. Nevertheless, adverse effects begin during childhood. Smoking alters pulmonary structure and function in young adults and adolescents. Adverse respiratory effects

have been documented in children smoking as little as one cigarette per week.⁵ Pregnant adolescents who smoke have an increased risk of delivering prematurely.³ Although less prevalent than cigarettes, smokeless tobacco also increases health burdens in young people due to periodontal disease.

A THEORETICAL BASIS FOR TOBACCO USE PREVENTION IN PEDIATRIC PRIMARY CARE

Primary care providers are particularly well-positioned to deliver tobacco use prevention messages. Declining perceptions of health risk from smoking have paralleled recent increases in youth smoking prevalence. In the youngest cohort assessed by the 1995 Monitoring the Future Survey, only 50% of 8th graders endorse a serious health risk from smoking one or more packs per day, and only 34% perceive a serious risk from the regular use of smokeless tobacco.¹ In contrast, anticipated negative outcomes from smoking, particularly fear of adverse health effects, have been reported to be a significant factor in early refusals of offered cigarettes.⁶ Health care providers are therefore uniquely positioned to influence children's perceptions of health risk.

Health care providers who care for children are trained to tailor messages to their patients' cognitive development. Messages about the health risks of smoking that are delivered to children must be developmentally appropriate. Rational decision-making processes are dependent upon a child's ability to abstract or to anticipate consequences.⁷

Health care providers can also use their influence and expertise to address peer, family, and psychological issues which affect tobacco use. Children who are exposed to parents, older siblings, or peers who smoke are at high risk for initiating use,² and peer influences have been established as important factors in susceptibility to tobacco use.⁸ Perception of social norms mediates the influence of peers. Youth smokers underestimate the disapproval of peers and overestimate peer and adult smoking rates.⁹ Self-efficacy to resist peer pressures to use tobacco is also an important predictor of youth smoking. These findings suggest that preventive interventions address children's perceptions of social norms and promote strategies to enhance self-efficacy for resisting

peer influences. For many children, tobacco use may be a dysfunctional coping strategy in the presence of psychosocial vulnerabilities such as depressed mood, attention and hyperactivity difficulties, high perceived stress, and body-image concerns. All are associated with increased risk of current and future smoking.¹⁰ Sussman et al. note a relationship between children's experiences in managing stress and their intentions to smoke.¹¹ Stressful family factors, such as parental indifference, poor parent and child communication, and low adolescent involvement in family decision-making processes, have been associated with adolescent smoking.¹² Pediatricians and family physicians can identify children's psychological vulnerabilities and parental and family difficulties and assist both parents and children to manage them.

To date, the tobacco use prevention interventions achieving the best behavioral outcomes have been school-based social influences models.² Programs that explicitly counter environmental pro-tobacco pressures and use cognitive-behavioral strategies to develop tobacco refusal skills consistently outperform programs based on information deficit and affective education models.¹³ Analysis of successful programs led to NCI recommendations that school-based interventions incorporate (1) information on the short-term consequences of smoking, (2) information about social influences, and (3) resistance skills training.¹⁴ These strategies are similar to adult smoking cessation strategies.¹⁵

THE ADVANTAGES OF TOBACCO USE PREVENTION IN PEDIATRIC PRIMARY CARE SETTINGS

Routine tobacco use prevention counseling by pediatric health care providers is a promising, but underdeveloped, channel of intervention. Patient receptivity to counseling about tobacco use provided in the context of pediatric health care is supported by reports that children and their parents are interested in health information from their providers¹⁶ and that they believe their personal physicians to be credible sources of health advice.¹⁷ Pediatric health care providers need to be proactive in identifying and addressing tobacco use, as adolescents are unlikely to initiate discussion even when engaging in risky behaviors.¹⁸ The average annual number of health care visits for children ages 5-11 and 12-17 are 3.5 and 3.3, respectively.¹⁹ These visits provide opportunities for pediatric providers to intervene to prevent and reduce tobacco use. Continuity of care allows both child and parent to experience a committed, caring relationship with the care provider; within this context, preventive messages may be especially influential.

Children with parent-reported behavior problems are likely to have more medical visits than those without.²⁰ This subset of children may be important to target for intervention, since they tend to affiliate with tobacco using peer groups.²¹ Adult smokers report that advice from physicians is an important motivation for quitting, and well-documented trials demonstrate that adult smokers who received even brief advice to quit are significantly more likely

to quit during the following year than smokers who had not received this advice.²² Because of the enormous public health benefit from even minimal interventions, the Agency for Health Care Policy and Research has issued strong practice guidelines that every patient, at every visit, be assessed for tobacco use and that smokers be strongly advised to quit.¹⁶

Pediatric health care providers have a rich tradition of support for psychosocial interventions. Professional pediatric and family medicine practice guidelines advocate early and repeated tobacco use prevention counseling.

BARRIERS TO TOBACCO USE PREVENTION IN PEDIATRIC PRIMARY CARE SETTINGS

Unfortunately, actual counseling rates of adolescent smokers in primary care settings appear to be low, with only 50% of adolescent smokers recalling any queries or advice about tobacco use from patients or nurses.²³ Although physicians as a group support the goal of reducing tobacco use, they experience numerous barriers to implementation of routine counseling.²⁴ Barriers include lack of knowledge and skills in delivering motivational counseling or smoking cessation counseling, limited time, lack of patient education resources, and limited use of office staff to assist in delivering counseling interventions.

OVERCOMING THE BARRIERS

We believe that these barriers may be overcome in pediatric primary care settings. Brief, effective smoking cessation counseling skills can be taught to pediatric health care providers. Moreover, in adult primary care settings, investigation of physician preventive care behaviors has demonstrated a clear link between performance and the presence of supportive office systems.²⁵ These systems are most successful when offices use a team approach to address key elements of care delivery: identification, assessment, patient education and counseling, patient follow-up, and monitoring and feedback to staff of the delivery of the intended services.

In the meantime, health care providers who see children are encouraged to use existing opportunities to provide anticipatory guidance to preadolescent and adolescent patients about tobacco use and also to advise those young patients who smoke to quit. To this end, we have recently applied for a grant to test a practical application of the model in Rhode Island.

References available from editor, on request.

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Michael Goldstein, MD, is Acting Psychiatrist-in-Chief, Miriam Hospital, and Associate Professor of Psychiatry and Human Behavior, Brown University School of Medicine, and has been a member of the Tobacco Control Planning Committee of the RI Department of Health.



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	October 1997	12 Months Ending with October 1997	
	Number	Number	Rates
Live Births	1,204	13,400	13.5*
Deaths	825	10,013	10.1*
Infant Deaths	(7)	(88)	6.6#
Neonatal deaths	(6)	(73)	5.4#
Marriages	884	8,184	8.3*
Divorces	241	3,040	3.1*
Induced Terminations	449	5,592	417.3#
Spontaneous Fetal Deaths	39	985	73.5#
Under 20 weeks gestation	(32)	(905)	67.5#
20+ weeks gestation	(7)	(80)	6.0#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	April 1997	12 Months Ending with April 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	271	3,433	346.7	4,331.0
Malignant Neoplasms	200	2,499	252.4	6,652.5
Cerebrovascular Diseases	40	604	61.0	919.5
Injuries (Accident/Suicide/Homicide)	30	350	35.3	6,213.5
COPD	36	455	45.9	272.5**

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

NINETY YEARS AGO

[APRIL, 1908]

Dr. John V. Shoemaker discusses the problem of gastralgia. He presents the case of a 41 year-old housewife with a history of severe attacks of pain in the stomach which were relieved by pressure upon the epigastrium; and, in the absence of any abnormal physical signs, negative gastric analysis, and a negative urine, he diagnosed gastralgia due to neurosis. Gastralgia, in Dr. Shoemaker's view, is "due to her hysteric conditions and the slight anemia present." The treatment, he states, should be chiefly hygienic and dietetic. The patient was admitted and all oral feedings replaced by fluids per rectum beginning with the white of an egg in a half ounce of whiskey. On the sixth hospital day, oral feedings were begun. By the 24th hospital day all pain, nausea and vomiting had ceased.

The problems of aural nystagmus and vertigo are discussed by Joseph F. Hawkins, MD. He summarizes much current work on the physiology of aural nystagmus and its intimate association with aural vertigo. He lists the various tests, including the use of tuning forks, to establish the nature of the underlying defect which, in most cases he claims, is found in irritation of the semicircular canals.

The biographies of 14 Rhode Island physicians who died during 1907 are listed. Average age at death was 57.1 years; the youngest was 26 years [contracted scarlet fever while an intern at Rhode Island Hospital]; the oldest, 74 years. Six of the 14 were born in Rhode Island.

Rules for admission to the Rhode Island State Sanatorium [for tuberculous patients] are outlined.



FIFTY YEARS AGO

[APRIL, 1948]

The conquest of puerperal infection during this past century is described by Edward S. Brackett, MD. His historical summary includes the observations and etiological surmises of Avicenna, Ramsbotham, Oliver Wendell Holmes, Ignaz Semmelweiss, and Louis Pasteur. More dramatic than words were Semmelweiss' 1847 demonstration at Vienna Lying In Hospital that rudimentary asepsis measures reduced the frequency of puerperal sepsis dramatically. The author rates the Semmelweiss discovery in the same category as the Jenner smallpox vaccine.

Peter F. Harrington, MD, discusses the frequency and demography of tuberculosis in Providence. He concludes that tuberculosis, with only about 250 new cases per year, is under satisfactory control in Providence. He notes too that the reduction in available beds for such patients means that more active cases will require home treatment.

Earl F. Kelly, MD, Banice Feinberg, MD, Francis V. Corrigan, MD, and John F. Kenney, MD, present the narrative text of a symposium on rheumatic fever conducted at Memorial Hospital. For a nation just completing a lengthy war, they point out that one-half million men were rejected for military service during World War II and 31,000 cases in the military were diagnosed with rheumatic fever or its sequelae. The magnitude of the problem can best be appreciated by statistics from Rhode Island's Department

of Health: In the preceding six years, the Clinic accepted 505 children with proven or suspected rheumatic fever and its complications.

Ira V. Hiscock, ScD, outlines the responsibilities of the hospital administrator to other community health agencies.

TWENTY FIVE YEARS AGO

[APRIL, 1973]

Professor Salvator E. Luria presents an essay on science, technology and responsibility. Specifically, the author considers the mixed blessings of genetic technology.

Roswell Johnson, MD, discusses whether alcoholism is a disease. He demonstrates that every major professional organization in medicine has agreed that alcoholism is clearly a disease warranting appropriate therapies. He concludes: "It is not readily apparent that the concept has strong support in health care delivery systems in Rhode Island in either the public or the private sector."

The problem of alcoholism and traffic safety is summarized in a paper by Laurence Senseman, MD. Nathan Sonkin, MD, discusses the hidden faces of alcoholism as a multi-system disease which may masquerade as various medical or emotional disorders.

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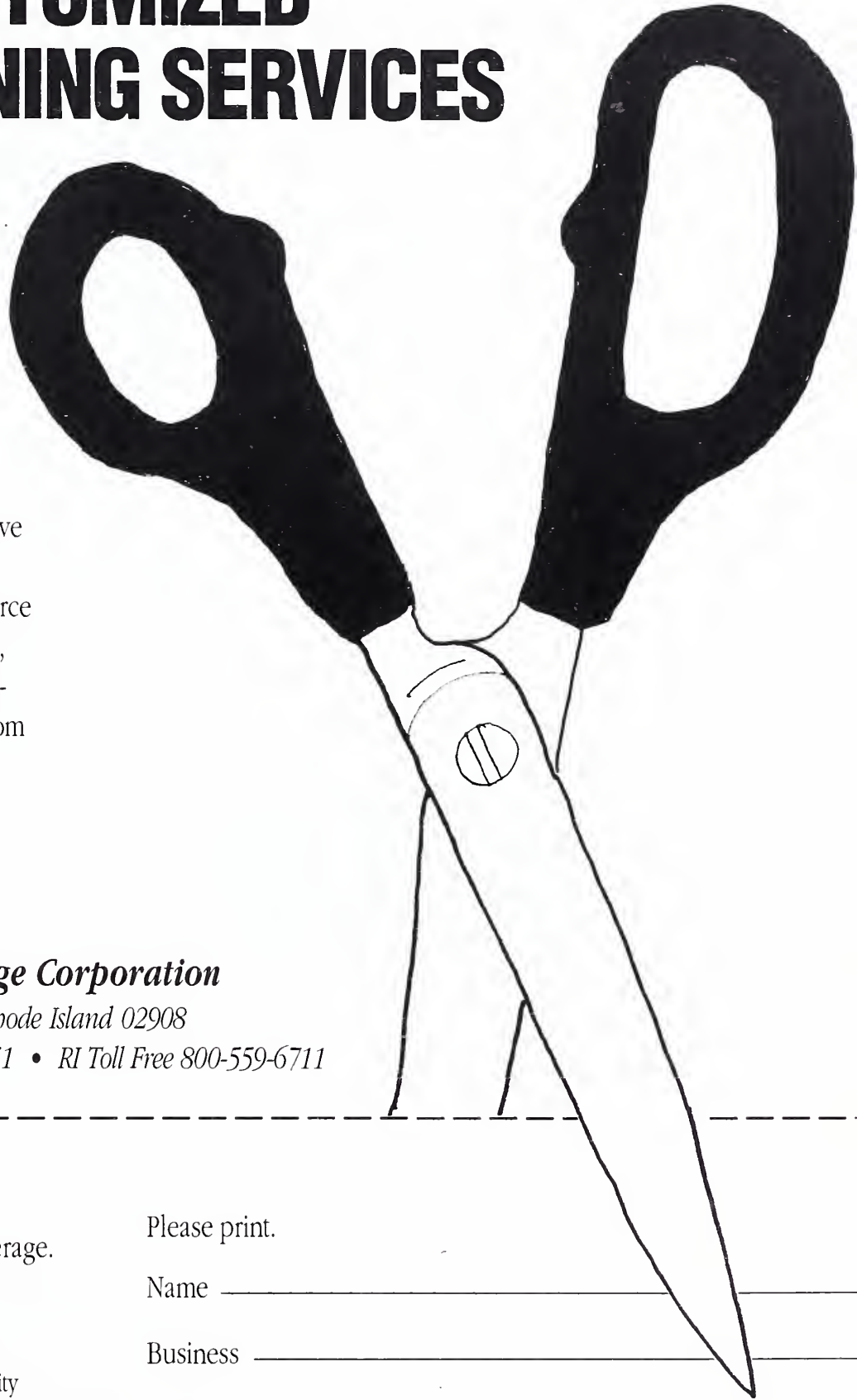
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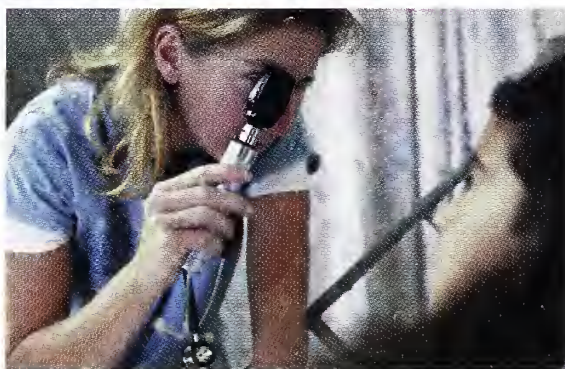
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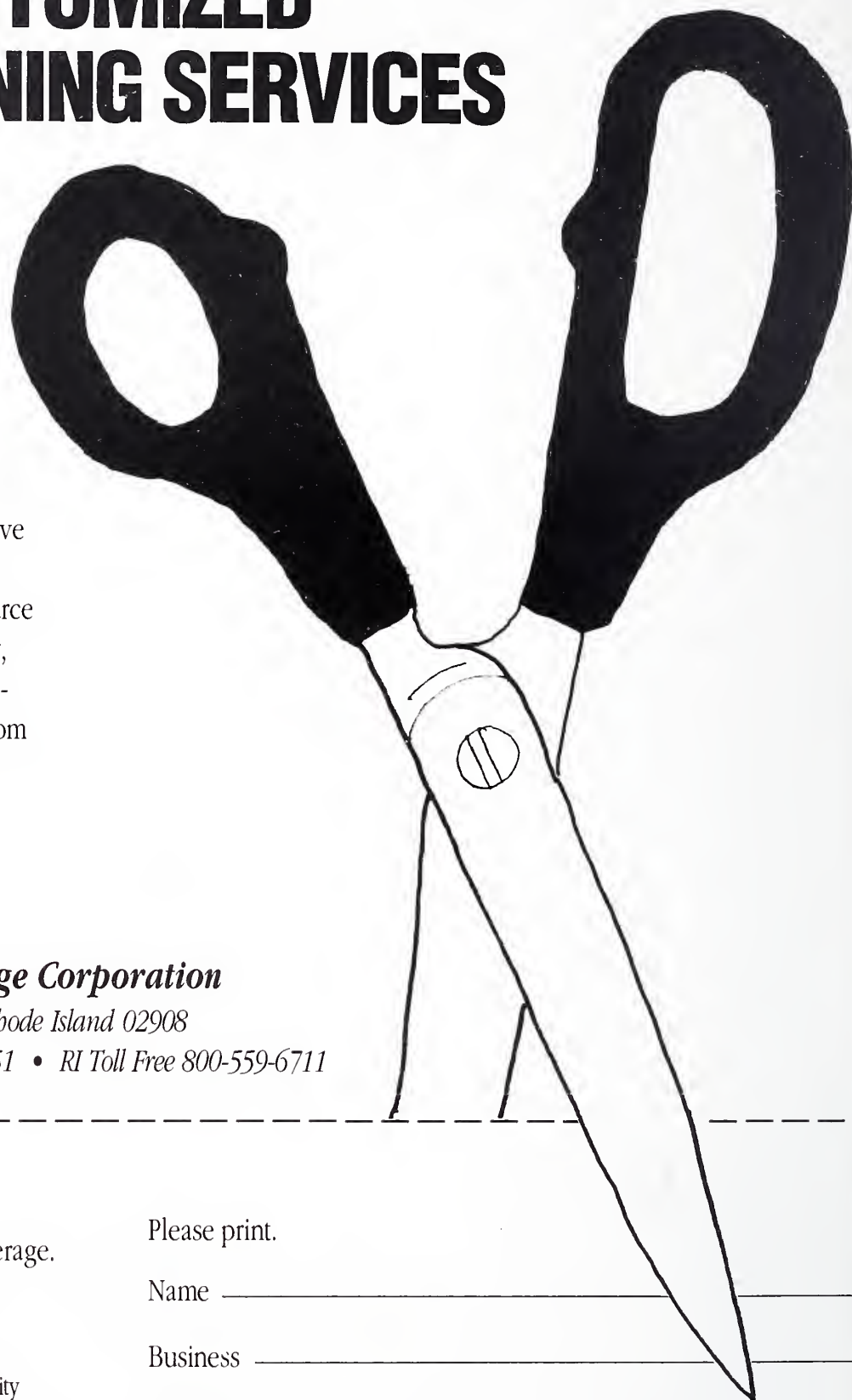
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COMMENTARIES

Musculoskeletal Disease

Disorders of the musculoskeletal system are the most frequent causes of functional impairment in the United States. They are the leading cause of time lost from work and consume 2.5% of the Gross Domestic Product in direct medical care costs. Their enormous social impact includes indirect costs of care.

Many chronic musculoskeletal conditions are more prevalent in older people. As the baby boom generation ages, musculoskeletal diseases will become more prevalent, with attendant increases in societal and direct and indirect economic costs. This will tax the ability of the health care community to provide cost-effective care and strain the existing social support networks.

One way to deal with the increasing prevalence of chronic musculoskeletal conditions is to develop cost-effective interventions to reduce the extent of functional disability and, therefore, their economic and social impact. The contributions to this issue of *Medicine & Health / Rhode Island* demonstrate that early definitive intervention - both medical and surgical - can often reduce morbidity and mortality, improve function, and reduce direct and indirect health care costs. Examples include the treatment of osteoporosis and the decrease in fracture rate, joint replacements for arthritis, early interventions to prevent crippling joint disease, and spinal surgery. Our understanding of connective tissue biology and the pathophysiology of musculoskeletal diseases has increased substantially in recent years. Within the next few years we can expect an explosion of technology transfer from the laboratory to the clinic. This will include new classes of anti-inflammatory medications, the biological restoration of joint function

including cartilage transplantation, the introduction of growth factors to influence healing, techniques to manage chronic pain and new biomaterials including biocomposites, to name just a few. These and other techniques, devices, and procedures offer great promise to alleviate suffering, restore function and personal independence, but will require evaluation of their outcomes and cost-effectiveness.

As a group, patients with chronic musculoskeletal conditions are relatively immobile and often dependent upon family members or social support networks. New ways of delivering health care to these patients are required so that these new technologies can be applied appropriately. Perhaps in more than any other disease category, traditional medical disciplines are giving way to a multidisciplinary approach. Optimal musculoskeletal care will be given in an interdisciplinary environment, preferably in a single physical setting. In this way, care can be coordinated so that diagnosis is expeditious and treatment interventions are integrated. Patient travel and scheduling difficulties are reduced. Patients will appreciate the expedited care with minimal inconvenience. Insurers will recognize the cost-effectiveness of interventions which preserve patients' independence while reducing overall health care costs. The various musculoskeletal specialists will be able to interact as a group with the patient's primary care physician to minimize disability and morbidity.

This issue seeks both to indicate the scope of the problem of musculoskeletal diseases and to highlight some of today's cost-effective interventions.

I describe the impact of the early diagnosis of hip pain in hip joint preservation with new conservative surgi-



cal procedures which appear to decrease the need for hip replacement in osteonecrosis of the femoral head. Since hip replacement in patients ages 40-45 will require revision arthroplasty at some point (or points) in the patient's life, preventing or retarding hip replacement would be expected to decrease the morbidity and costs of revision arthroplasty. Howard Hirsch reviews the well-established documentation of the cost effectiveness of total hip replacements in older patients with osteoarthritis. Joint replacement has been the single most effective treatment for arthritis, allowing hundreds of thousands of individuals to remain productive and independent. Placing these interventions into context, Deborah Ciombor describes the impact of the anticipated increase in the prevalence of musculoskeletal conditions. Joseph Tucci describes the role of the early diagnosis and pharmacological intervention for the restoration of bone mass in osteoporosis. This appears to have resulted in a reduction in the incidence of fractures with their attendant morbidity and mortality and the social and economic costs of institutional care. Finally, Beverly Walters and Gerhard Friehs discuss surgical treatment for spinal stenosis in elderly patients, once thought poor candidates for surgery, but now able to gain a respite from pain.

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Hold the Mayo

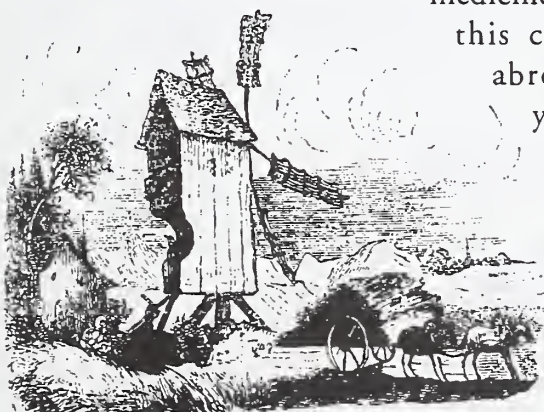
The word, Mayo, conveys different meanings to different people. A lunch counter cook hears it as a shorthand reference to mayonnaise; an Irishman knows it as the name of the meagerly populated western county, province of Connaught, in the Old Country, a name traced back to a pre-Norman monastery called Maio; but to physicians, it is the family name of three eminent surgeons - a father and two sons - who, toward the end of the 19th century, created a remarkable group practice in the small prairie town of Rochester, Minnesota.

William Worrall Mayo, the senior founder of what eventually became the Mayo Clinic, was born in Manchester, England, and migrated to the United States at age 26. He taught school for a few years before apprenticing himself to an Indiana surgeon. When the Civil War needed physicians, he volunteered and was assigned as provost surgeon for southern Minnesota. And when Mayo returned to civilian life he remained in the area establishing his office in the small southern Minnesota community of Rochester.

Rochester was a prosperous agricultural community in Olmsted County but with no hospital. A devastating tornado in 1883, however, convinced its citizens to construct one. The institution, managed by the local Sisters of St. Francis, was called St. Mary's Hospital; and Mayo was its first surgeon. By 1890 he was joined by his two sons, William J. Mayo ["Dr. Will"] and Charles H. Mayo ["Dr. Charlie"] and the three maintained a productive and extremely busy surgical practice. By 1903 their informal alliance had been transformed into a cooperative practice as they incorporated radically new diagnostic instruments such as X-ray machines and recruited numerous physicians in other specialties to create one of the first group practices in this country.

The three Mayos were convinced, from the beginning, that continuing education was an indispensable element in preserving their clinical competency. Accordingly, they each devoted their yearly vacations to intensive medical review courses in one or another school of medicine, either in

this country or abroad. This yearly ritual of going back to school became a requirement for the other



physicians who had joined their group endeavor. And much of the fortune amassed by the Mayos was eventually invested in creating the Mayo Foundation, an internationally famous graduate medical school now affiliated with the University of Minnesota.

The Clinic prospered and by its 75th anniversary had treated over 3.5 million patients during the course of 25 million clinic consultations. The Clinic, moreover, was more than a notable referral center; it also became the primary care facility for virtually the entire population of Olmsted County, some 100,000 men, women and children.

One of the earliest physician-recruits to the clinic was an internist named Henry S. Plummer. In addition to his clinical skills, Plummer had a genius for organizing information so that it might be readily and rapidly retrieved. Back in 1903 physicians generally kept their records in large ledger books with patient-entries chronologically arranged. The ledger method was adequate when the physician wanted to review his labors for a particular day or consider his appointments for the next day; but to follow the clinical course of a single patient required the scanning of many pages. The ledger book worked reasonably well for the isolated physician in a rural community since most relevant information was stored in his memory. But by the turn of the century the nature of medical practice was undergoing rapid change. It became increasing common for an individual to

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be delivered by an obstetrician, treated for childhood diseases by a pediatrician, have his appendix removed by a surgeon, and then, later in life, have his heart disease cared for by an internist. If the ledger system had prevailed, there was no way that anyone might have easy access to a person's entire medical history.

Plummer realized that each new medical encounter by the patient might be better understood if it could be built upon the accumulated information gathered during all prior medical encounters. He then devised a novel new mechanism called the patient chart, a folder containing individual sheets summarizing each interaction with the medical profession, thus incorporating the patient's accumulated demographic, diagnostic, surgical, and therapeutic profile. He also assigned a unique lifetime number to each patient so that his/her folder might be easily filed - and retrieved - from a central repository called a Record Room.

Plummer was seeking something more than mere neatness and record-keeping efficiency. He knew that there were valuable clinical lessons to be learned in patient records, lessons not only for the physicians immediately involved, but for all physicians. The information lying fallow was useless unless it could be retrieved and somehow distilled. Accordingly, he devised a numeric system such that each diagnosis might be cross-indexed. His system, for example, allowed a clinical investigator to quickly retrieve all cases of thyroid cancer and determine, in retrospect, who in the general population had been the most vulnerable, what had been the range of outcomes, and which of the many treatments employed proved to be most beneficial. He perhaps anticipated the thoughts of Edna St. Vincent Millay:

"Upon this gifted age, in its dark hour
Rains from the sky a meteoric shower of facts.
They lie unquestioned, uncombined,
Wisdom enough to leach us of our ill
Is daily spun, but there exists no loom
To weave it into fabric."

These precious tons of patient records are housed in a single newly constructed repository connected to the clinic buildings by underground pneumatic tubes ferrying patient charts back and forth. The zealously guarded patient records are protected by a sophisticated fire suppression system and much is now electronically stored, as well.

In any three year span, over 95% of the County population are being treated, or at least routinely examined, in the Clinic. Virtually every birth, every surgical procedure, every death, every autopsy in the County is recorded in the central files. These vast amounts of accumulating data permit searches [first by hand, then by mechanical sorting machinery and now by electronic means] to uncover inapparent patterns of disease. For example, has the incidence of disease X changed? If so, in which age group? Which gender is at greater risk? Is the disease associated with any particular geographic site or occupation or therapy or lifestyle? Is it correlated with some other climatic or epidemiologic factor? Which form of treatment has worked best?

Under one roof in Rochester, Minnesota, is an irreplaceable collection of billions of pieces of clinical information waiting for epidemiologists to uncover causal relationships, undertake risk factor analyses and plan therapeutic trials leading to a more rational practice of medicine. The three Mayos have indeed left a memorable and enduring heritage in the wheat fields of Minnesota.

— Stanley M. Aronson, MD

Information for Contributors

Medicine & Health/Rhode Island welcomes submissions from members of the Rhode Island health care community. Submissions can fall into one of three categories:

CONTRIBUTIONS

Contributions should report on an issue of interest to clinicians in the state: new research, treatment options, collaborative interventions, review of controversies. The maximum length of submissions is 2500 words; the maximum number of footnotes is 15. (The Journal is not the venue for an exhaustive literature review). Tables, charts, and figures should be camera-ready. Photographs should be black and white. (Slides are not accepted.)

CREATIVE CLINICIAN

Clinicians are encouraged to submit brief (no more than 1200 words) descriptions of cases that defy textbook analysis. Photographs, charts, and figures may accompany the case; footnotes should not exceed 6.

POINT OF VIEW

This column gives readers an opportunity to share their perspective on any issue facing clinicians. The topic is broad:

it could, for example, include ethics, health care policy, and/or relationship with patients. Maximum length is 1200 words.

The format of submissions is as follows:

The title page should include name, affiliation, address, phone, fax, and email. A brief abstract should appear on a separate page. References should be numbered sequentially in the text, and listed separately at the end of the document (not the end of each page).

For Contributions and Point of View, please submit 4 hard copies of the document, with a disk (Microsoft Word or Text), to the managing editor, Joan Retsinas, PhD, 344 Taber Avenue, Providence, RI 02906.

For Creative Clinician columns, please submit 3 hard copies of the document, with a disk (Microsoft Word or Text), to Anthony Mega, MD, Miriam Hospital, Providence, RI 02906.

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BOOK REVIEWS

Medicine & Health/Rhode Island will review books authored by Rhode Island physicians. Publishers should send a copy for review to the managing editor.

Importance of the Early Diagnosis of Hip Pain:

New Approaches to Hip Preservation in Osteonecrosis

Roy K. Aaron, MD

Osteonecrosis of the femoral head (ONFH) refers to the death of osteocytes with subsequent trabecular fracture leading to femoral head collapse and secondary hip joint arthritis. ONFH is common, with approximately 20,000 new cases per year. Pain is the most common clinical symptom. However, in many hips a subclinical phase exists which is asymptomatic but in which imaging studies are positive. Both subclinical and clinically apparent ONFH exhibit a high likelihood of clinical and radiographic progression, culminating in joint incongruity and arthritis, often requiring total hip replacement.

Total hip replacement is useful for end stage ONFH. However, the mean age of patients with ONFH is 40-45 years and long-term results of hip replacement in these patients have exhibited a substantial failure rate. Therefore, procedures which preserve the hip and avoid or delay replacement have particular appeal.

Hip preservation is possible only in the early stages of the disease. Recognition of early ONFH, in turn, depends upon an understanding of the time course of progression of untreated disease, the identification of individuals at risk for developing ONFH, and the prompt investigation of hip pain with sensitive and specific diagnostic techniques.

Significant advances have been made in understanding aspects of ONFH which bear on the ability to preserve the hip with conservative treatment. These include:

1. More complete understanding of the natural history including the determination of the time course of progression and factors which predispose to especially rapid progression.

2. New concepts of etiology and pathophysiology. The relative risks of

the presumed etiological factors, corticosteroids and alcohol, have been established. A unified concept of pathogenesis has been advanced. The role of hypofibrinolysis and thrombophilia has emerged as a central issue in the pathophysiology of ONFH and has implications for the identification of at-risk individuals.

3. A multimodality approach to diagnosis has elucidated the relative diagnostic specificity and sensitivity of a number of clinical tests and has established the primary role of MRI in diagnosing ONFH. Radionuclide scans may be particularly important in multifocal ONFH, particularly to diagnose clinically inapparent but inevitable hip involvement.

4. New therapeutic interventions, notably biologically augmented core decompression, have improved hip preservation and reduced the need for hip replacement in early lesions. Since these procedures are effective only in early, pre-collapse hips or hips with minimal collapse, early diagnosis and staging are essential. The diagnosis of early ONFH depends upon the identification of the at-risk individual and the prompt investigation of hip pain. Screening of high-risk asymptomatic individuals may be appropriate.

The radiographic features of ONFH have been staged qualitatively by Ficat. The staging system refers to a pre-radiologic stage (stage 0 or I, depending on the absence or presence of pain, respectively), in which imaging studies such as bone scan or MRI are positive, but conventional radiographs are normal. Stage II hips display the stereotypical mottled sclerosis and lucency without fracture in the femoral

Abbreviations Used:

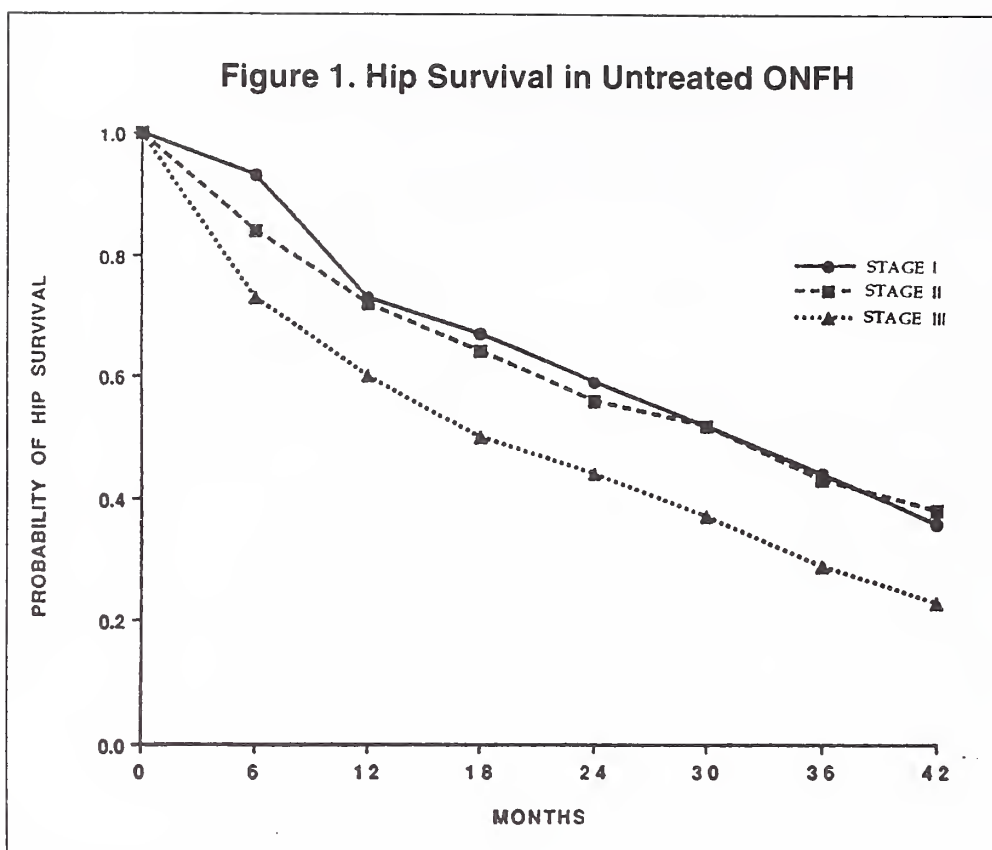
BMES	bone marrow edema syndrome
BMP	bone morphogenic proteins
CD	core decompression
CT	computed tomography
DBM	decalfied bone matrix
EMF	electromagnetic field stimulation
MRI	magnetic resonance imaging
ONFH	osteonecrosis of the femoral head
PAI	plasminogen activator inhibitor
RAP-C	resistance to activated protein C
TGFβ	transforming growth factor
tPA	tissue plasminogen activator

head. Stage III consists of hips in which a subchondral or segmental fracture is visible with varying degrees of collapse and loss of sphericity of the femoral head. Stage IV is synonymous with osteoarthritis.

NATURAL HISTORY

Recent studies have delineated the mean time to clinical and radiographic failure at a follow-up of 2-3 years. Twenty-one studies involving 819 hips followed for a mean of 34 months, demonstrated satisfactory clinical outcomes in only 22%.¹ Clinical failure and hip loss to arthroplasty occurred in 65% of stage I, 69% of stage II, and 87% of stage III hips. From these studies it has been concluded that ONFH progresses regardless of the radiographic stage of severity at the time of presentation.

Studies from our group have examined the time course of clinical and radiographic progression and those clinical and radiographic characteristics that are associated with more rapid hip failure.² Clinical progression occurred regardless of the stage of initial presentation. By 36 months follow-up, 54% of stage I, 66% of stage II, and 73% of stage III hips required total hip replacement. Survival analysis revealed that



Clinical progression. Hips surviving have not undergone either total hip replacement or core decompression. Reproduced with permission with modification².

the time course of hip loss was more rapid than previously assumed with a mean failure of 23 months in stage I and II, and 17 months in stage III hips (Figure 1). This was accompanied by 83-94% radiographic progression in all stages. These data, together with those previously reported, indicate that clinical and radiographic progression occurs rapidly, even in the early stages of the disease. These data support aggressive early therapeutic intervention in all patients with osteonecrosis of the femoral head, regardless of clinical or radiographic stage at presentation.

Controversy has existed as to the role of clinical or radiographic characteristics in influencing the risk of clinical failure. Notably among the clinical features studied, only age > 40 years in stage III hips was associated with more rapid progression. Corticosteroid intake at pharmacologic levels, while certainly a risk factor for the occurrence of osteonecrosis, is not associated with more rapid progression.² With regard to radiographic risk factors, initial lesion size and extent of collapse were related to clinical outcome in specific ways. Large lesions are clearly associated with more rapid disease progression. However, because 2/3 of hips with lesions occupy-

ing < 50% of the femoral head progress, the prognostic value of this radiographic measurement was low. Stage III hips with minor degrees of collapse on initial x-rays have a better prognosis than do hips with more extensive collapse.

*... the ability to preserve
the hip depends upon
early diagnosis of
osteonecrosis of the
femoral head, before
severe subchondral
collapse.*



ETIOLOGY

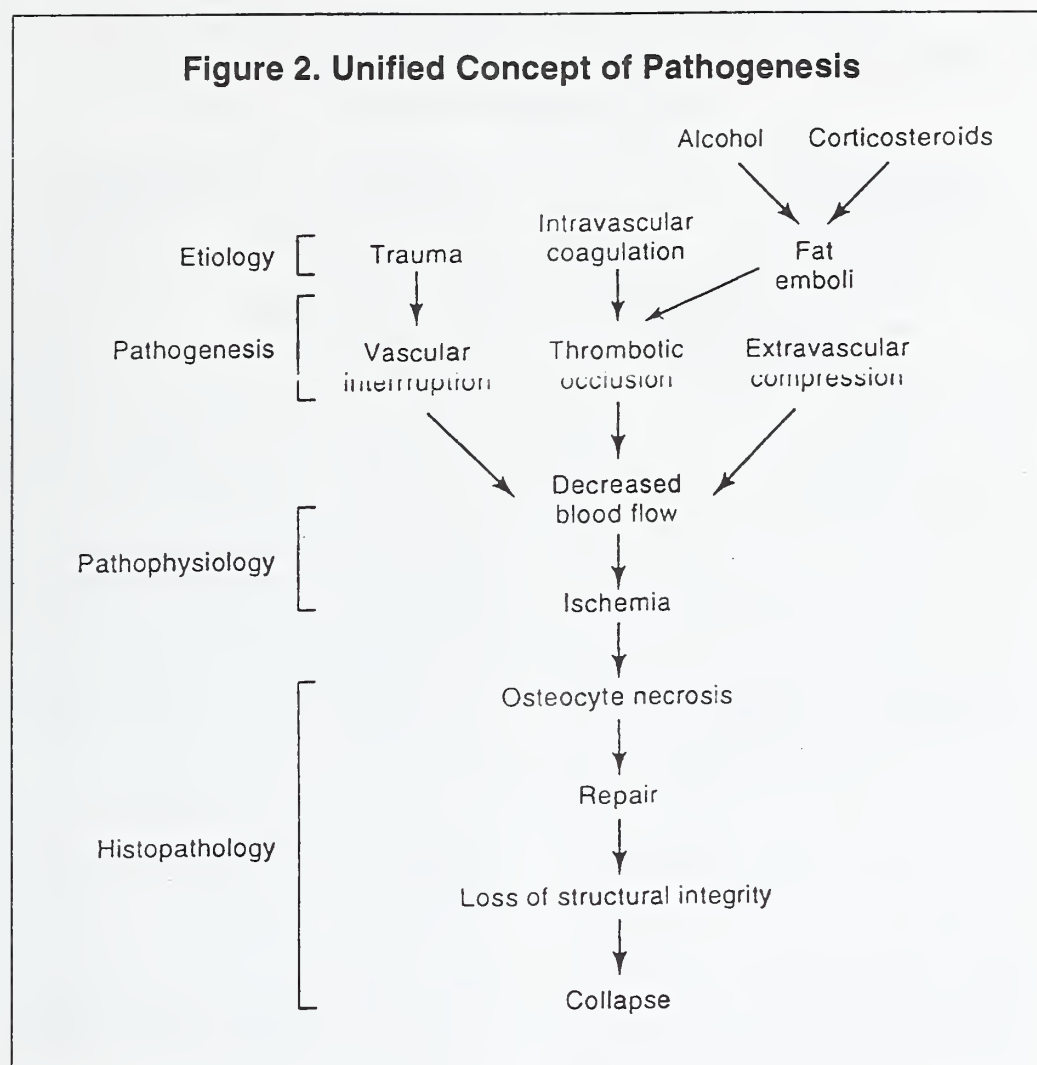
A number of medical conditions have been associated, as presumed etiologies, with ONFH. It is difficult to assess the frequency of each etiology because of the varying demographic composition of reporting centers. In most series up to 20% of ONFH are idiopathic. The importance of recognizing etiological associations relates to the early identification of the at-risk individual and the early diagnosis of hip

pain. Diagnostic screening of at-risk individuals may be appropriate to identify early ONFH.

Steroid-associated ONFH accounts for 10% - 30% of cases, depending upon the center. Earlier concerns about distinguishing the effects of corticosteroids from those of the underlying associated diseases, particularly in patients with vasculitis or renal failure, have largely been resolved. A large meta-analysis of 22 series studying steroid-associated ONFH found no correlation between the underlying disease and the osteonecrosis.⁵ Although it is not certain that the use of steroids presents equal risks in all conditions, attention has been focused on a threshold dose of steroids in determining the risk of developing ONFH. Dose has been expressed as mean daily dose, peak dose, duration of exposure, and cumulative (total) dose. Most studies have suggested a correlation of ONFH with mean daily or peak dose rather than with cumulative dose or duration of therapy. These studies have suggested that high mean daily or peak doses, even for short duration, present significant risks for ONFH. Data collated from several studies reveal that most patients with ONFH in whom mean daily steroid dose was reported received doses > 20 mg./day and that dose is generally regarded as presenting a significant risk for ONFH. Analysis of 22 studies of steroid-associated ONFH demonstrated a 4.6 fold increase in ONFH for every 10 mg./day increase in oral steroid intake.⁵ A strong correlation was described between mean daily dose and ONFH risk but none between peak dose and ONFH.

ONFH associated with alcohol intake comprises 10-40% of cases in most series. Individuals consuming more than 400 ml. of alcohol/week have been shown to be at a 9.8-fold greater risk of developing ONFH (Table 1).¹⁰ The risk increased with the cumulative "drink-years" (weekly alcohol consumption x number of years of drinking). The relative risks from two studies, respectively, were < 4000 drink-years (3.2 and 2.2); 400 to 10,000 drink-years (8.3 and 9.7); and > 10,000 drink years (13.1 and 12.9).

Figure 2. Unified Concept of Pathogenesis



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PATHOGENESIS

Studies of the pathophysiologic events leading to osteocyte necrosis have focused on the vulnerable microcirculation of the femoral head and the consequences of ischemia. A unifying concept of the pathogenesis of ONFH has been presented and emphasizes the central role of vascular occlusion and ischemia leading to osteocyte necrosis (Figure 2).¹ Current evidence suggests that intravascular coagulation with microcirculatory thrombotic occlusion is the most likely final common pathway for non-traumatic ONFH resulting from a variety of etiologi- cal associations.

Recent studies have demonstrated the presence of hypofibrinolysis and thrombophilia in patients with ONFH.¹ Hypofibrinolysis is usually associated with low levels of tissue plasminogen activator (tPA), elevated levels of plasminogen activator inhibitor (PAI), and, often, high levels of lipoprotein A. Decreased levels of the antithrombotic proteins C or S, and resistance to activated protein C (RAPC), decrease the regulation of the

prothrombotic factors V and VIII. Both hypofibrinolysis and thrombophilia are accompanied by an increased incidence of thrombotic events. Within the past 2 years, several reports have linked hypofibrinolysis and thrombophilia to ONFH through the pathogenic mechanism of hypercoagulability and thrombotic occlusion of femoral head circulation.^{6,7} In one study, 100% of patients with idiopathic ONFH had coagulation defects. 75% had elevated PAI and low tPA with a corresponding inability to initiate fibrinolysis; 25% had elevated lipoprotein A. Of patients with ONFH associated with specific etiologies, 78% had elevated lipoprotein A levels. In a second study, 83% with idiopathic ONFH had coagulation defects, the majority having hypofibrinolysis due to elevated lipoprotein A. Of patients with ONFH associated with specific etiologies, 62% had a variety of coagulation disorders. These data suggest that individuals with an underlying genetic predisposition to thrombosis, when presented with environmental challenges such as corticosteroids and alcohol, which themselves may dispose to microcirculatory thrombosis, may develop clinical disease. It has been suggested that patients at risk for ONFH, such as those starting corticosteroids or with high alcohol intake, undergo coagulation testing and screening for ONFH. In addition, when heritable thrombophilias are diagnosed in patients with ONFH, close relatives should be tested, because approximately 50% will also have a coagulation disorder that may manifest itself as a thrombotic event, such as thrombophlebitis, pulmonary embolus, ischemic stroke, or myocardial infarction.

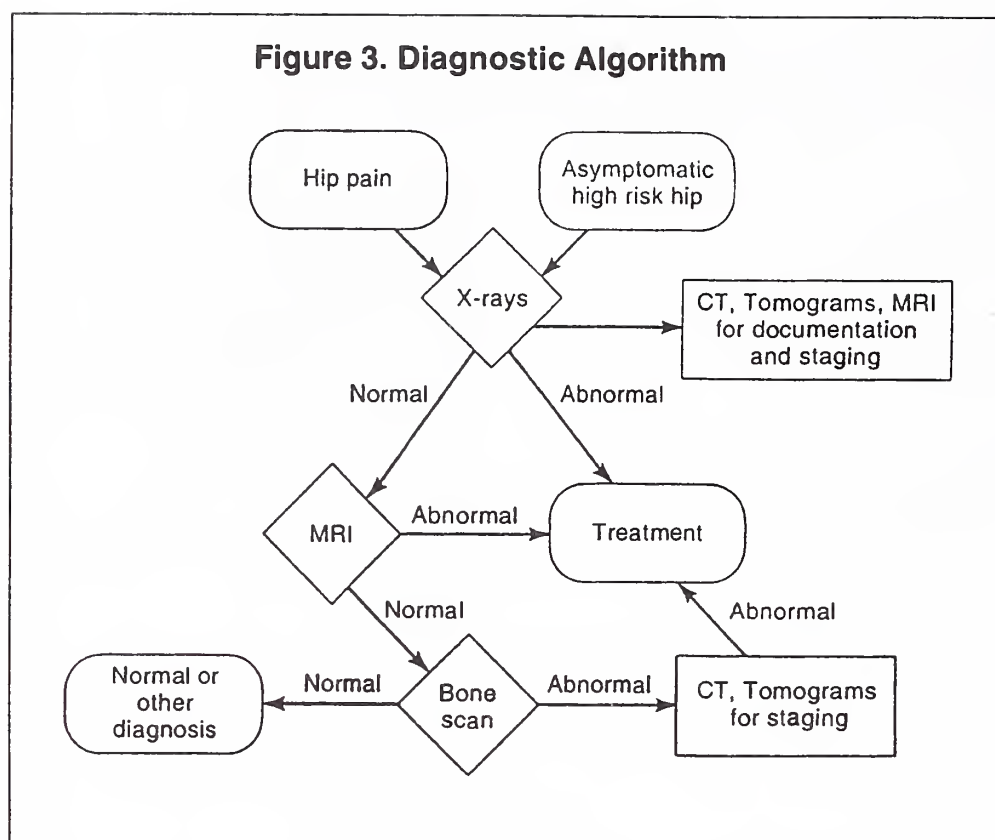
DIAGNOSIS

Diagnostic approaches to ONFH must recognize that (1) there is a pre-radiologic stage of ONFH; (2) ONFH may be asymptomatic on radiographic presentation; and (3) multifocal ONFH may present initially in the shoulder, knee or ankle but eventually always involves the hip. The ability to preserve the hip depends upon the early diagnosis, before structural collapse of the femoral head.

Studies of multiple diagnostic modalities have identified MRI as the most sensitive and specific technique for the detection of ONFH. Technetium bone scans are particularly useful for surveying multiple joints, particularly when the patient has an atypical presentation of osteonecrosis in the shoulder or ankle. Studies of multifocal osteonecrosis demonstrate inevitable, but often asynchronous, involvement of the hip.⁴

The diagnosis of ONFH on coronal MRI sections can be made with approximately 90% specificity and 95% sensitivity.¹ The earliest abnormality is a low-intensity signal on both T1 and T2 weighted images. In more advanced lesions, the T1 images continue to show low intensity signal and the T2 images may exhibit signals of alternating high and low intensity, the so called "double line sign." However, a high intensity signal on T2 weighted images is not absolutely necessary for the diagnosis of ONFH and one may occasionally see a low intensity signal on both T1 and T2 weighted scans. From several studies, a diagnostic algorithm has been pro-

Figure 3. Diagnostic Algorithm



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posed (Figure 3).^{1,9,12} The index hip may present with pain or may be an at-risk hip such as the contralateral hip in a patient with ONFH. AP and frog lateral x-rays are obtained. If the radiographs are positive for ONFH, the disease should be further staged by CT scan or tomography for the purpose of planning treatment. If the radiographs are negative, an MRI or bone scan should be done. The MRI is generally preferred because of its superior specificity and sensitivity. Technetium bone scans, on the other hand, permit the detection of ONFH in joints other than the hip.

The major differential diagnosis of ONFH is the bone marrow edema syndrome (BMES), or transient osteoporosis. This condition occurs in the same age range as does ONFH and may also be bilateral. It presents with pain, an antalgic gait, and a loss of range of motion. The MRI provides an important diagnostic distinction between ONFH and BMES.⁸ In ONFH, low signal intensities observed in both T1 and T2 weighted images. In BMES, decreased signal intensity is seen in T1 images and increased signal intensity is observed in T2 images, reflecting increased marrow water content.

NEW THERAPEUTIC INTERVENTIONS

The usual conservative procedure utilized for ONFH is core decompression. However, the literature has shown (1) considerable variability in the clinical and radiographic results and (2) limitation of satisfactory clinical results to pre-collapse lesions. The percentage of treated patients experiencing a satisfactory clinical outcome varies. Satisfactory results have been reported in 38 - 100% of stage I, 42 - 82% of stage II, and 0 - 73% of stage III lesions. Some of this variability may be due to biomechanical consequences of the location, diameter, and depth of the core track. Relatively minor variations in track placement may have major mechanical implications relative to subsequent femoral head collapse. In addition to this variability in outcome, most studies indicate that the therapeutic benefit of core decompression is limited to precollapse lesions. Satisfactory outcomes have been reported in 78 - 89% of stage I, 62-66% of stage II, and 34 - 47% of stage III lesions. Because a repair process has been observed in osteonecrotic femoral heads, efforts have been undertaken to biologically augment this repair process by using the core track as a portal through which to

gain access to the necrotic zone and through which neo-vascularization and new bone formation can be stimulated.³

Biological augmentation of core decompression has been accomplished with four techniques: autogenous allograft, decalcified bone matrix, bone morphogenetic protein - 2, and electrical stimulation. Results with autogenous cancellous graft have been interesting but have never been directly compared to core decompression alone. Bone morphogenetic proteins (BMP) are a group of evolutionarily highly conserved signalling molecules related by sequence homology to TGF β . In mammals, BMPs are regulators of bone and cartilage formation. Two studies have been reported using recombinant human BMP-2 introduced through core decompression tracks in ONFH. These studies have demonstrated an increase in local bone formation and a decrease in the volume of the necrotic zone. Clinical data have not yet been presented. Decalcified bone matrix (DBM) is a highly osteoinductive derivative of whole bone. It contains a number of growth factors and morphogens and stimulates the differentiation of mesenchymal stem cells to osteoblasts.³

We have carried out core decompression plus DBM (CD + DBM) in 28 hips with ONFH followed for a mean of 34 months and compared the results to CD alone in 90 hips followed for 40 months. (Table 2).³ In stage II hips, a small but clinically significant improvement in hip survival (16%) was observed in hips treated with CD + DBM compared to CD alone. Radiographic progression was retarded as well with 67% of CD + DBM, and 44% of CD, hips exhibiting stable x-rays. In stage III hips, a two-fold increase in hip survival was observed in CD + DBM

Table 1. ONFH and alcohol

Dose (ml/wk)	Risk
0	1.0
<400	3.3
400-1000	9.8
>1000	17.9

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Table 2. Hip Preservation with Biologically Augmented Core Decompression³

Treatment	Stage	n	Hip Survival
CD	II	43	29 (67%)
	III	47	16 (34%)
CD + DBM	II	12	10 (83%)
	III	16	11 (69%)
CD + EMF	II	13	10 (77%)
	III	13	9 (69%)

treated hips compared to CD alone. This was particularly notable since there is no generally accepted treatment for stage III lesions. Radiographic progression, however, was unaffected.

Electrical stimulation has been clinically useful in enhancing bone repair in a number of conditions including spinal fusions, osteotomies, bone graft incorporation, and fracture non-unions. Electrical signals stimulate the local production of BMP, TGF β and IGF-II. In addition, recent data suggest that appropriately configured electromagnetic fields may decrease osteoclastic bone resorption and maintain bone mass, possibly by interfering with parathyroid hormone receptor signalling.³

We have reported results with a group of patients treated with core decompression plus electromagnetic field stimulation (CD + EMF). We utilized this technique in 26 hips followed for a mean of 44 months and compared the results to the group of 90 hips treated with CD alone followed for a mean of 40 months.(Table 2). In stage II, no significant increase in overall hip survival was observed but a major improvement in radiographic stability was noted in the CD + EMF group. Notably, radiographic stabilization was increased from 44% in the CD group to 77% in the group treated with CD + EMF. This is particularly noteworthy in that it describes the prevention of subchondral fracture and collapse. In stage III hips, a two-fold improvement in clinical outcome was observed similar to that seen with treatment with CD + DBM and, similarly, suggests the possibility of treating lesions with femoral head fracture and limited collapse.

CONCLUSIONS

In recent years there has been a significant improvement in our understanding of ONFH, including the identification of the at-risk individual and the development of sensitive and specific diagnostic techniques. ONFH is now recognized to progress rapidly even in "early" lesions. Understanding etiologic and pathophysiologic factors as well as those clinical and radiographic characteristics which are associated with more rapid progression has permitted the identification of individuals at risk for ONFH and for more rapid disease progression. These issues are particularly important since newer hip - preserving treatments markedly improve hip retention over previous techniques. However, the ability to preserve the hip depends upon early diagnosis of ONFH - before severe subchondral collapse. This in turn depends upon the identification of at-risk individuals and the early application of diagnostic modalities to investigate hip pain. The clinician should maintain a high index of suspicion in the at-risk individual and investigate hip pain promptly and vigorously.

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Total Joint Replacement: A Cost-Effective Procedure for the 1990s

Howard S. Hirsch, MD

"Total joint replacement is the single greatest advance in the treatment of arthritis..."⁸ These are not the words of a boastful orthopaedic surgeon or even of an unusually thankful patient, but of H. Ralph Schumacker, an eminent rheumatologist from the University of Pennsylvania. Before the advent of modern total hip replacement in the 1960s and modern total knee replacement in the 1970s, people with severe arthritis of weight-bearing joints had limited options. Even today, patients who suffer from advanced arthritis of their hip or knee must choose between accepting serious impairment even with maximal nonsurgical management, versus proceeding with joint replacement. This explains why total hip and total knee arthroplasty are among the most common major surgeries in the United States.

CLINICAL AND ECONOMIC CONCERNS

While the orthopaedic literature is replete with traditional clinical studies that document excellent pain relief and near normal function in middle

aged and older patients with joint replacement, this does not answer satisfactorily all the questions currently posed to the healthcare community regarding these procedures. Third party payers, who pay most of the direct costs for joint replacement, demand that the efficacy of these procedures be proved with outcome studies. Such studies emphasize data such as global surveys of the patient's overall function, sense of well-being, and personal opinion as to the efficacy of the surgery. Traditional clinical studies placed more emphasis on physicians' objective measurement of results and subjective opinions regarding quality of results (Table I). Moreover, payers now demand that providers prove not only that their proposed interventions result in successful outcomes, but that they do so in a cost-effective manner. This article will present a focused literature review that documents the beneficial outcome and cost-effectiveness of total joint replacement.

Abbreviations Used:

MACTAR	McMaster-Toronto Arthritis Patient Preference Disability Questionnaire
QALY	quality-adjusted life years
SIP	Sickness Impact Profile
TKA	total knee arthroplasty
WOMAC	Western Ontario and McMaster University Osteoarthritis Index

OUTCOME STUDY DATA

In order to recommend any procedure on a routine basis, particularly for an illness that is not life-threatening, the physician must be confident of a beneficial outcome in the great majority of cases. Laupacis et al. recently evaluated total hip replacement using multiple indices of outcome including walking measurements, pain scales, Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Sickness Impact Profile (SIP), as well as more traditional measures of hip function including Harris Hip Scores, and Merle d'Aubigne scores. They found that, using virtually any of these measures, total hip replacement resulted in successful outcome. Most improvement had occurred by three months, although some ensued thereafter. The only negative finding of note was that joint replacement in this study population did not significantly improve the work capacity of the population studied.⁵ This is not surprising, considering that the average age of patients in this study was 64 years, and most had already reached the usual age of retirement. Liang et al. assessed cost-effectiveness in a large group of joint replacement patients by tracking patient charges and measuring outcome using various global scales. They concluded that joint replacement was cost-effective and that patients with the greatest degree of

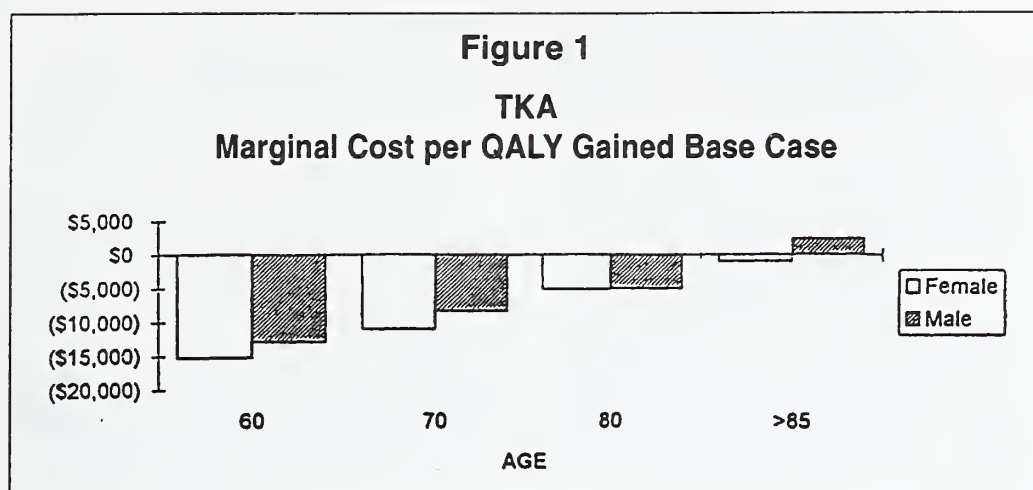
Table I

Clinical Scoring Systems for Joint Replacement

Merle d'Aubigne Hip Score	Harris Hip Score
HSS Hip and Knee Scores	Knee Society Score

Outcome Based Scores used to Evaluate Joint Replacement

Western Ontario and McMaster University Osteoarthritis Index (WOMAC)
Sickness Impact Profile (SIP)
Time Trade-Off Technique
McMaster - Toronto Arthritis Patient Preference Disability Questionnaire (MACTAR)



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pre-operative impairment benefited most from the procedure.⁶ Notably, the researchers did not compare the cost-effectiveness of joint replacement to other treatments.

ECONOMICS: THEORETICAL AND PRACTICAL

While non-operative intervention does not offer the possibility of dramatic alteration of the course of endstage arthritis in weight-bearing joints, ideally one would like to prove, through prospective randomization, that joint replacement is cost-effective with respect to outcome when compared to non-operative management. Ethical considerations probably preclude such a study. Gottlob et al., however, recently reported the results of a study which used a sophisticated model to compare the cost-effectiveness of total knee replacement versus non-operative care in an elderly patient disabled by severe osteoarthritis. Their model predicted that total knee replacement was dramatically more cost-effective than non-operative management for such a patient. Comparative cost between surgical and non-surgical care was the "marginal cost per quality adjusted life-years gained". Figure 1 shows predicted savings with surgical care for most patients. Even when the parameters of their model were varied such that the prospective patient was older and less likely to have long-term benefits from a successful surgical procedure, total knee replacement remained favorably cost-effective in patients up to 85 years old.²

... current economic pressure on the health care market has prompted payers to demand that providers prove not only that their proposed interventions result in successful outcomes, but that they do so in a cost-effective manner.



Actual clinical outcomes studies have corroborated the results predicted by the above model. Boettcher conducted an outcome study on total hip replacement in patients 80 and older. While they did have a higher complication rate after surgery, as expected, the cost savings resulting from the decreased need for nursing home care after surgical patients had

recovered resulted in favorable cost-effectiveness, even in this elderly population.¹ Zicat et al. compared outcomes in knee arthroplasty patients greater and less than 80 years of age. Despite 8% higher costs of rehabilitation in the older population, the surgical procedure remained cost-effective.⁹

CURRENT ISSUES

Since these studies and others clearly document that total joint replacement is beneficial and cost-effective for patients with severe arthritis, even well into the later years of life, it is likely that it will remain the preferred treatment option for most patients with advanced arthritis of the hip and knee. Recognizing this, payers have begun to demand that doctors, patients, and hospitals cooperate to control the costs of these procedures. Two principal means have been proposed to accomplish cost control: hospitals have used various policies to limit the selection of available devices. Particularly in older patients, surgeons are now expected to use less expensive, usually cemented total joint implants as much as possible. This concept, called "demand matching," presumes that if less expensive, cemented devices are used in older patients with shorter life expectancies, these devices will provide sufficiently durable service. Since hospitalization costs constitute another expensive resource needed by joint replacement patients, restricting length-of-stay has been the other primary means of cost reduction. While at one time patients were often admitted on the evening prior



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to total joint replacement and stayed in the hospital for up to two weeks, patients now are admitted on the morning of surgery and often leave in 3-4 days. Even though many of these patients are already being discharged to extended care facilities, some insurance companies and hospital administrators want to decrease the usual length of hospitalization further.

At some point one must question whether any further attempts to control costs through the above-mentioned measures will improve cost-effectiveness. Healy and Finn compared the cost of total knee replacement in 1983 with that in 1991. While the overall cost of the procedure decreased 15% when adjusted for inflation, the savings resulted predominantly from an inflation-adjusted 46% decrease in hospitalization costs, which are attributable to the much shorter length of stay. Implant costs during this same period increased dramatically. Devices used in 1991 cost 59% more than those in 1983, even after adjustments for inflation.³ This suggests that control of implant costs provides a major key to cost-efficient joint replacement.

Unfortunately, the concept of demand matching does not address the question of whether the less expensive devices are truly clinically comparable to the more recently designed, more expensive implants. Furthermore, if more sophisticated implants result in a decreased need for subsequent revision procedures, this may diminish the comparative cost-effectiveness of less expensive implants, even in an older population whose longevity continues to increase. Rorabeck et al. recently reported the results of a prospective, randomized study comparing the costs of cemented versus cementless primary total hip replacement. The operation was judged cost-effective using a wide range of clinical outcome measures. Actual cost savings with the presumably less expensive, cemented devices were minimal.⁷

While Healy's study showed that the dramatic decrease in length-of-stay has decreased the overall expense of joint replacement surgery, payers and hospital utilization review departments are pressuring doctors and patients to decrease length of stay even more. From the hospital's perspective, earlier discharge, even to an extended care facility, will lower costs. Killeen and Burt recently evaluated the direct costs of joint replacement associated with hospitalization for up to one week followed by discharge home, compared with early discharge to an extended care facility. Not surprisingly, they found that when patients were kept for up to one week so that they could be discharged directly to their homes, the direct costs of joint replacement were lower than if they had been discharged to other facilities.⁴ This documents that early discharge from the hospital followed by placement in other facilities results in cost shifting but not cost savings.

SUMMARY

Total hip and knee replacement have been shown to be beneficial procedures not only by traditional clinical studies but by modern outcome measures as well. The cost-effectiveness of total joint arthroplasty compares favorably with non-surgical treatments for patients with advanced arthritis of the hip and knee. While cooperation is necessary among all participants in the health care system to provide total joint replacement in a cost-efficient manner, dramatically short lengths of hospitalization and limitation of surgical implant selection are unlikely to provide any real cost savings. Total hip and knee replacement as currently performed will continue to offer cost-effective relief to patients with advanced arthritis of their major weight-bearing joints.

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The Scope of Musculoskeletal Disease into the Next Millennium

Deborah McK. Ciombor, PhD

Arthritis and associated disorders of the musculoskeletal system comprise the most frequently reported causes of functional impairment affecting the adult population in the United States. Over one third of US adults are affected by musculoskeletal signs such as joint swelling, limitation in motion, or pain on motion.¹ Musculoskeletal conditions accounted for approximately 18% of new visits to physicians. As the percentage of the population over the age of 65 increases, the relative impact of musculoskeletal diseases will increase as well. According to the Bureau of the Census (1990), the percentage of the population over 65 is increasing at a rate 2.5 times faster than the general population. By the year 2030, it will comprise over 70,000,000 Americans, or greater than 20% of the projected population, compared to 12.5% in 1990.¹ Since the highest prevalence of musculoskeletal disease occurs in individuals 65 years and older, physicians in the next century will see a massive increase in this disease.

The impact of musculoskeletal conditions can be measured in three categories: 1) the physical and social impact resulting from pain, limitation

in mobility and activity of daily living, loss of independence and reduced quality of life; 2) direct medical expenditures for diagnosis and treatment; 3) the indirect costs associated with decreased participation in the labor force, loss of productivity and wages that result from activity limitations.³

INCIDENCE AND PREVALENCE OF MUSCULOSKELETAL CONDITIONS

The National Health Interview Survey (NHIS) indicates that the self-reported incidence of "arthritis" (broadly defined) in the US increases from 193/1000 for men ages 45-64, to 481/1000 for men ages 75 and over. A total for all self-reported musculoskeletal conditions is 530/1,000 in males of all ages and 728/1,000 in females of all ages. In addition, between 1990 and 1992, chronic musculoskeletal conditions ranked highest in chronic conditions overall in prevalence in the civilian non-institutionalized population (35 million cases reported by ICD-9 codes).⁴ Musculoskeletal impairments are most prevalent in the

45-64 age group: 64% of these impairments can be attributed to greater involvement in the lower extremity or in hip dysfunction. They are the leading cause of activity limitation as well, resulting in approximately 1.5 billion restricted activity days largely for back or spine impairments and for lower extremity or hip disease.³ In the recent NHIS, approximately 42% of persons with musculoskeletal conditions - more than 17 million - were limited in their daily activities. These individuals represent

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
ICD	International Classification of Diseases
GNP	Gross National Product
NHDS	National Hospital Discharge Survey
NHIS	National Health Interview Survey

46% of all persons with activity limitations.⁴

In 1992, approximately two-thirds of all working-age adults in the US were in the labor force. By contrast, only 42.6% of working-age adults who had musculoskeletal conditions worked. In 1992, 42 million persons with musculoskeletal conditions represented 16% of the total US population, but accounted for nearly 30% of the 1 million physician visits and 33% of all hospital admissions.

ECONOMIC IMPACT OF MUSCULOSKELETAL CONDITIONS

The economic burden of musculoskeletal conditions was \$149.4 billion in 1992 (48% due to direct medical care costs).⁵

From 1990 to 1992, musculoskeletal conditions caused 315 million individuals to seek care from physicians each year. The NHIS estimates that 41 million persons with musculoskeletal conditions made an annual average of nearly 8 visits per person to a physician. Additionally, musculoskeletal conditions accounted for 8.26 million hospital admissions each year.

Since approximately 42% of individuals with chronic musculoskeletal conditions are functionally limited to some degree,⁵ they are prone to work loss: three-quarters leave work before the normal age of retirement. Com-

TABLE 1

1994 Chronic Conditions Per 100 Individuals over the Age of 65

Arthritis - 50
Hypertension - 36
Heart Disease - 32
Hearing Impairment - 29
Cataracts - 17
Orthopaedic Impairments - 16
Sinusitis - 15
Diabetes - 10

Compiled from American College of Rheumatology and Arthritis Foundation data, 1997, and National Center for Health Statistics, 1994.

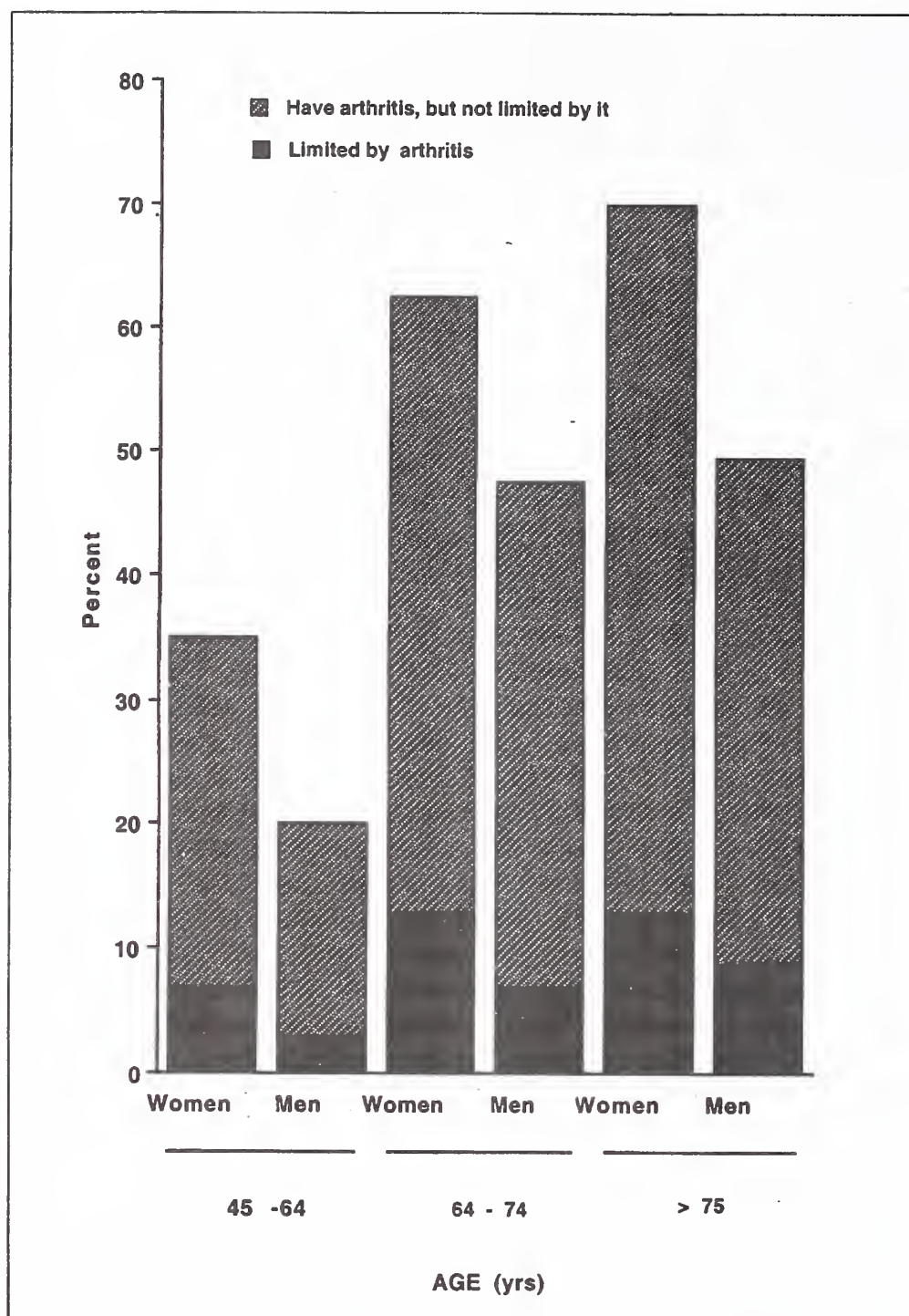


Figure 1: Activity Limitations of Adults Who Self-Report Arthritis
Source: Compiled from Reports by the Centers for Disease Control and Prevention, the National Center for Health Statistics, and the National Health Interview Survey (1993-1994).

munity-based studies of persons with a broad range of musculoskeletal conditions find work disability rates of 38 to 72%, depending upon the mix of symptoms.⁹

ARTHRITIS

The relative impact of arthritis and related rheumatic diseases is not generally recognized. Osteoarthritis and related rheumatic conditions rank as the leading cause of disability among persons age 65 and older.⁷ In 1990, nearly 40 million Americans, 1 in 7, had arthritis. Prevalence rates were 49.4% for persons over 65 years, com-

pared with 5.1% for persons equal to or younger than 44 years and 0.5% for children under the age of 16; 2.7% of the population in North America have arthritis while circulatory problems affect only 1.4% of the population and respiratory problems only 0.65%. By the year 2020, the prevalence of arthritis will increase to 59.4 million Americans (18.2% of the population). Studies by the Arthritis Foundations of the United States and Canada found that 50% of elderly patients older than 65 years had arthritis (Table 1).

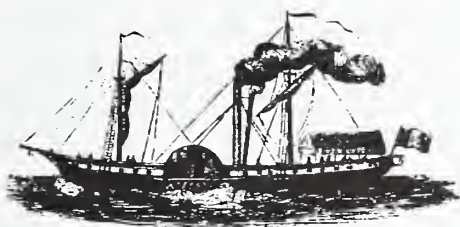
Risk factors are age, gender, eth-

nic/racial background, occupational history, repetitive physical activity, trauma, abnormal biomechanics, genetic predisposition, obesity and increased bone density. Reports have documented marked ethnic, age, and gender differences in the prevalence rates of arthritis and related activity limitations (Figure 1). Osteoarthritis is two times as prevalent in females, who account for twice as much health care utilization and undergo total knee arthroplasty at a frequency rate two times that of men in the same age group. Projections have been based on the average annual arthritis prevalence rate from 1989 - 1991 NHIS survey compared to the US population. During 1989 - 1991, arthritis was either first or among the top four self-reported chronic conditions among all ethnic groups in the United States.

The Medical Outcomes Study (National Center for Health Statistics, 1994-1995), conducted among persons presenting to physicians' offices, compared the impact of nine chronic conditions on quality of life. On average, arthritis ranked fourth in limitations in physical and mental health function, third in social function and eighth in pain. These data, however, were not weighted for prevalence. The study indicated that while the morbidity of arthritis is limited, its prevalence results in the greatest amount of lost function overall. A person with severe rheumatoid arthritis, for example, may lose as many as 9 months of healthy life per year.

To evaluate the impact of chronic conditions, medical economists ask respondents how much they would pay to avoid all burdens of the disease including non-market ones. Comparing several chronic conditions and the number of quality-adjusted life years lost, respondents were asked to evaluate the impact of each such year lost in monetary terms. Patients reported that they would pay \$10,747 (1992 dollars) to avoid arthritis.

The impact of these figures extends beyond the direct cost of medical care for several reasons: 1) even among working age adults more people have arthritis along with other diseases



than have arthritis alone; 2) the probability of activity limitation in persons with arthritis is higher than in other chronic conditions; 3) the absolute number of working-age persons with arthritis and arthritis-related disability indicates that this is not just a disease of the elderly; and (4) risk factors appear to operate differently for women than men and for different sites.

Individuals with arthritis have a lower labor force participation rate than persons with other chronic diseases. This is particularly true when co-morbidity and limitation of physical abilities exist. Men with arthritis, co-morbidity and activity limitation had a 40% lower work force participation than men with arthritis alone, 42% lower rates than all working-age men and 45% lower rates than men without any chronic condition. The impact is greater for women. Women with arthritis, co-morbidity and activity limitation had a 45% lower work force participation than women with arthritis alone, 52% lower rates than all working-age women and 54% lower rates than women without any chronic condition. Women with arthritis also have much lower labor force participation rates than women limited by other chronic conditions, an effect not replicated in men.⁸

For the last decade, two groups have debated the impact of declining mortality rates on overall public health. One group has projected a pandemic of chronic disease and disability if frail individuals live longer; the opposing group has projected a compressed period of morbidity, due to a rise in the age at onset of chronic diseases. Data suggests that the prevalence of chronic diseases is indeed rising - and that the overall economic and social impact of arthritis is disproportionately high.⁶ The impact of arthritis will expand even if prevalence rates stagnate, because the extent of arthritis and related disability is growing faster than the population.

BACK PAIN

In the United States, back pain is one of the most frequently reported musculoskeletal problems and is the second most frequently reported symptom leading persons to visit a physician. Back pain has been reported as the second leading cause of work absenteeism in the United States (after upper respiratory tract conditions) and results in more lost productivity than any other medical condition. Back pain is also a significant contributor to functional disability and has been reported as the leading cause of limitation of activity among young adults. According to the National Health and Nutrition Examination Survey II, 75% of people ages 45-64 reported having low back pain of at least two weeks' duration within the last year. Approximately 12% of those with low back pain reported features of sciatica. In 1994, nearly 14.3 million office visits resulted from back pain.

The NHIS for 1990-1992 estimates that 41 million persons with musculoskeletal conditions made an average of nearly 8 visits per person yearly to a physician.



Annually, back pain results in over 39 million restricted activity days and 12.1 million bed disability days. The majority of the cases were reported in men (55.7%). Back injuries accounted for 26.2% of closed Workers' Compensation cases.

OSTEOPOROSIS

The prevalence of osteoporosis is difficult to gauge for several reasons: 1) some progressive loss of bone mass appears to accompany normal aging; 2) bone loss can be caused by other disease processes; 3) the bone mass at one site is not necessarily correlated with the bone mass at other sites; and 4) bone mass measurements have only recently been reliable and reproducible. Despite these difficulties, the prevalence of radiologically defined osteoporosis is believed to be directly related to age and increases from 18% for women ages 45-49 to 89% for those 75 years and older. Osteoporosis is associated with bone pain and with fracture, particularly of the hip, vertebrae, distal radius and pelvis.²

Hip fractures are a major cause of the disability and mortality from osteoporosis. The probability of returning to previous levels of activity and independence following hip fracture decreases with senescence, making this a major source of direct medical costs in the elderly. The cost of hip fractures was estimated at \$13.8 billion for the year 1995. The direct costs comprise over 80% of the total. This represented nearly 5% of all Medicare expenditures for that year. As the

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"boomers" age, these numbers are likely to rise.

MUSCULOSKELETAL INJURIES

The average number of medically attended injuries in the years 1985-1988 was 29.4 million. By 1992, musculoskeletal injuries resulted in 42.7 million visits to physicians' offices, a 45% increase in 4 years. New problem office visits to physicians, due to injury, occurred at a higher rate among men (6.2 per 100 population) than among women (4.9 per 100 population), primarily due to higher injury rates among men. This rate of increase is likely to continue unabated as the "boomers" progress through the health care system, despite the changes in practice patterns and hospital stays.

Currently, there are 850,000 fractures per year in those age 65 or older. Fracture care accounted for 3% of all Medicare cost in 1992. This accounted for \$13.8 billion for direct medical costs in 1995. Again, this amount will increase at a rate similar to that of the population increase.

In 1983, musculoskeletal injuries represented 25% of the reported occupational illness in the private sector. By 1988, that percentage had increased to 48%. Total costs for musculoskeletal injuries for the year 1988 were \$26.1 billion. The annualized costs for 1997 are anticipated to top \$40 billion. This may be a gross underestimate as the incidence of occupational

injury, cumulative trauma and repetitive stress syndromes continues to increase. Sizable increases were noted specifically for carpal tunnel syndrome and disorders related to tendons, such as tenosynovitis and deQuervains disease.² According to the CDC, approximately 47% of carpal tunnel syndrome cases are work-related.

CONCLUSIONS

Musculoskeletal conditions occur more frequently than many other chronic conditions, including heart disease, cancer, stroke, chronic lung disease, and diabetes.⁷ Because many musculoskeletal conditions are age-related, the "boomers" retirement should spark a surge in the incidence of musculoskeletal diseases with the attendant rise in direct and indirect costs.

We are not prepared for the increasing prevalence or impact of musculoskeletal impairments. The health care system, already overburdened, cannot accommodate the projected needs. Currently, musculoskeletal diseases and injuries account for 15.6% of Medicare costs. By 2002, that number is expected to reach 20%.

These demands on health care delivery will be accompanied by a revolution in the way medical information is handled, catalogued and disseminated. The explosion of medical information means that to "be current" is beyond the capacity of any single specialty.

The need for change should spur innovative ways of delivering health care. The traditional interactions among physicians will require updating. Patients in the 21st century will require an integrated multidisciplinary approach to health care as multiple specialists bring their expertise to bear. The role of the primary care physician will be important in the

coordination of care. Evaluations and outcome studies of technological innovations and ways of delivering health care will be important in defining effective and efficient health care.

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Osteoporosis Update

Joseph R. Tucci, MD

Albright originally defined osteoporosis as a condition in which there was "too little bone in the bone." Subsequently, osteoporosis was defined by the presence of nontraumatic vertebral fractures. Today the World Health Organization defines it as a skeletal disease characterized by low bone mass and microarchitectural deterioration of bone with a consequent increase in bone fragility and susceptibility to fractures.¹ Bone mass accounts for approximately 80% of bone strength. Generally, the lower the mass, the greater the risk of fracture and the greater the need for therapeutic intervention. Recently, with the advent of precise instrumentation, it is possible to diagnosis osteopenia and osteoporosis prior to the development of fractures.

Albright described osteoporosis as postmenopausal in women up to age 65 years, senile in older women and men, and idiopathic in which neither menopause, age or any other cause could be established. Recently, the term type I osteoporosis was suggested for trabecular bone loss associated with menopause and the term type II osteoporosis, for subsequent age-related trabecular and cortical bone loss.² These are considered to be forms of primary or involutional osteoporosis. The secondary forms are those in which bone loss is related to, for example, glucocorticoid therapy, hyperthyroidism, and malabsorption.

This review will focus on postmenopausal and age-related bone loss.

STATISTICS/IMPACT OF OSTEOPOROSIS

Osteoporosis is the most common disease of bone and its incidence is increasing in many countries. These increases are greater than what one would expect simply on the basis of an increasingly aged population as evi-

denced by the increases in age-adjusted incidence of fragility fractures. Osteoporosis affects approximately 25 million Americans, 20 million of whom are women. Almost 80% of these women are undiagnosed and untreated, approximately 15% diagnosed and untreated, and less than 10% diagnosed and treated. The prevalence of osteoporosis is higher in Caucasians than in Asians and lowest in blacks and Mexican-Americans. In 1996 there were approximately 1.5 million osteoporotic fractures: 500,000 vertebral, 275,000 hip, and 250,000 Colles' fractures.^{1,3} The remainder were primarily fractures of the pelvis, humerus, and ribs. At age fifty, a woman has a 40% chance of one or more osteoporotic fractures over her lifetime. At that age her lifetime risk for a hip fracture is 17.5%, 15.6% for a vertebral fracture and 16% for a Colles' fracture. For men, the respective risks are 6%, 5%, and 2.5% - a risk equal to that of prostate cancer.⁴ For women the risk for one or more fractures is equal to the risk for ovarian, endometrial and breast cancer.

Osteoporosis is associated with considerable morbidity and mortality. With hip fractures, 20 to 40% of patients die, many within six months of the fracture.⁵ The greatest mortality is in nursing home patients. In women the lifetime risk of death due to hip fracture approximates that due to breast cancer. Mortality rates are higher in men than women, apparently related to comorbidities. Fifty percent of patients with hip fracture are permanently incapacitated, leaving at most 25% of patients with the mobility and independence that they had prior to their fracture. Morbidity and mortality associated with vertebral fractures

Abbreviations Used:

BMD	bone mineral density
DEXA	dual energy X-ray absorptiometry
FDA	Food and Drug Administration
LDL	low density lipoproteins
1,25-OHD	1,25-hydroxy vitamin D
25-OHD	25-hydroxy vitamin D
SERMS	selective estrogen receptor modulators

are often overlooked. With repeated fractures, whether clinically apparent or not, decreases in truncal height occur with the development of kyphosis and increasing approximation of the lower rib cage on the pelvis with subsequent compromise of cardiopulmonary and abdominal visceral functions. These changes together with comorbid conditions may explain an excess mortality of 20% in such patients.⁶

Osteoporosis accounts for more than 13 billion dollars of medical expenditures (1995). This compares with more than 17 billion dollars for the care of congestive heart failure (1993), more than 6 billion dollars for treatment of asthma (1990), and 6 billion dollars for the treatment of breast cancer (1996). In the United States, it is estimated that by the year 2020 the cost of hip fractures will exceed 60 billion dollars.^{1,7} The personal burden encompasses reduced quality of life through pain, limitation of physical and social activities, fear of falling, depression, a sense of hopelessness, and loss of self-esteem.

PATHOPHYSIOLOGY

In the adult, bone mass at any time reflects peak bone mass acquisition by age 25-30 years and subsequent loss related to menopause and later to age. Genetic factors account for 70 to 80 % of the variation in the acquisition of peak bone mass; nutrition, hormonal factors, physical activ-

ity and other lifestyle habits account for a smaller part.⁸ Illnesses and/or clinical disorders such as anorexia nervosa, delayed puberty, and exercise-induced amenorrhea during the growth years can affect bone acquisition, often with irreversible consequences. Skeletal mass is relatively stable until age-related bone loss begins in both men and women by age 40 years at a rate of .25 to 1 % per year. During the perimenopausal years and for five years after menopause, bone loss may occur at a rate of 1 to 5% per year.⁹ During this period a woman may lose up to 15% of her total bone mass. Menopausal loss is associated with decreased estrogen levels and increases in cytokines and osteoclastic activity. Subsequently, the accelerated rate of loss falls to less than 1% per year and then rises in the eighth decade of life.

CLINICAL MANIFESTATIONS

Osteoporosis has been called a "silent disease" due to its insidious nature. Many patients are not symptomatic and their osteoporosis is not discovered until they have developed an obvious fracture or vertebral compression fractures are noted on radiographic examination. Colles' fractures may or may not raise a question of underlying osteoporosis, while hip fractures are more likely to lead to such a diagnosis. A patient with an acute vertebral fracture may complain of localized pain in the mid to lower thoracic or lumbar spine, lasting for up to three months. Fractures may occur while bending, lifting, pushing, or even coughing. With repeated fractures of the thoracic spine one may gradually note height loss, curvature of the upper back (kyphosis), and intermittent back pain. Approximately one third of vertebral fractures are clinically apparent while the remainder are discovered later. Patients with a clinically inapparent fracture may have explained any acute back pain as a "strain." As noted, repeated vertebral fractures can adversely affect cardiopulmonary and abdominal visceral functions. Hip fractures may occur at the femoral neck or intertrochanteric region of the proximal femur. Where intertrochanteric

fractures are generally associated with falls, femoral neck fractures, particularly in the elderly, may occasionally occur with little or no trauma.

DIAGNOSIS/ASSESSMENT

Clinically, the diagnosis of osteoporosis is often made after a patient has sustained a fragility fracture, after a report of one or more vertebral compression fractures, or the finding of osteopenia on radiographic examination. Vertebral fractures can be of the central, wedge, or crush variety. Vertebral wedging is defined as a decrease in anterior vertebral height of more than 15 or 20%, while a crushed vertebra is characterized by decreases in both anterior and posterior vertebral heights. Central or biconcave deformities are related to reduction in midheight.

A clinician should consider a patient's risk factors.² The most important include the female sex, Caucasian or Asian race, maternal history of fracture, a previous fragility fracture, early menopause, estrogen deficiency and slender body habitus. Also important are behavioral factors, such as inadequate or suboptimal dietary calcium intake especially during the years of growth, a history of smoking or excess alcohol use, excess ingestion of caffeine or sodium and a sedentary existence. Another factor is propensity to falls, which may or may not be drug-related. Medications including glucocorticoids, excess thyroid hormone, loop diuretics, and anticonvulsants can have deleterious skeletal effects. The diagnosis of primary osteoporosis necessitates exclusion of a number of disorders which may give rise to secondary osteoporosis. In addition to a complete medical history and physical examination, the assessment of many patients may appropriately include measurements of serum calcium, phosphate, creatinine, alkaline phosphatase, thyroid stimulating hormone, 25-OHD levels and serum protein electrophoresis.

Bone mass measurements are important for the diagnosis of osteoporosis, and to determine the risk of fracture, the need for therapeutic intervention and to assess the response

to treatment. Generally, density measurements of the lumbar spine and proximal femur will adequately reflect the status of the skeletal mass. In the elderly, however, the lumbar spine may not be the site of choice due to arthritic changes and vascular calcifications that may artifactually increase the readings. With DEXA, bone mass measurements are expressed in standard deviations from mean values of sex and age matched controls (Z score) and in standard deviations from mean values for peak skeletal mass of a normal population of young adults at age 20-40 years (T score). Normal density values are less than one standard deviation below the young adult or peak mean value. The criterion for osteopenia is defined by a T score of -1 to -2.5 standard deviations below peak bone mass. Osteoporosis is defined by readings of more than 2.5 standard deviations below peak bone mass and severe osteoporosis when such readings are associated with fragility fractures. For menopausal women, BMD measurements are the best predictors of fracture. In the elderly, such measurements together with risk factors for falling are better at predicting fracture risk than BMD alone. For each standard deviation reduction in BMD even within the normal range, fracture risk doubles. For males, at least for the present time until more data are available, similar criteria have been suggested for estimating the presence of osteopenia and osteoporosis.

Biochemical markers which measure osteoclastic or osteoblastic activity appear to have utility in determining rates of bone turnover and they may have predictive value for fracture risk quite independent of bone mass measurements.¹⁰ Bone formation markers include bone-specific alkaline phosphatase, osteocalcin, and carboxy- and N-terminal peptides of procollagen type I. Bone resorption markers include pyridinoline and deoxypyridinoline and collagen type I N- and C-telopeptide cross-links. Some authors have suggested their utility in determining the need for therapy. At the present time their greatest potential utility is in assessing the skeletal

response to therapy. Whereas with therapeutic intervention, changes in bone mass may not appear for more than a year, significant decreases in resorption markers of 30% to 60% can be seen within two to three months of institution of therapy.

The indications for BMD studies, defined by the Scientific Advisory Board of the National Osteoporosis Foundation, include: 1. estrogen-deficient women whose decision regarding therapy will be guided by such readings; 2. patients with radiographic evidence of vertebral fractures or osteopenia; 3. patients receiving glucocorticoid therapy for more than a month; 4. patients with asymptomatic primary hyperparathyroidism to determine the need for surgical intervention. Currently insurers generally reimburse these measurements only for high-risk patients, or those with a disorder that may affect the skeleton, not simply for "screening."

THERAPEUTIC CONSIDERATIONS

The following are general recommendations for those with or without osteoporosis: balanced meals with adequate fruit and vegetable intake, avoidance of excess sodium and protein intake, sufficient intake of calcium. A diet chronically deficient in calcium may impact negatively on peak bone acquisition and later contribute to osteoporosis and fracture risk. The data are in keeping with a positive effect of calcium intake on bone mass through

inhibition of bone resorption.¹¹ If dietary intake of calcium is inadequate, supplements may be given (1500 mg of calcium per day) to estrogen-deficient women who are not candidates for estrogen replacement therapy. For women being treated with estrogen, 1000 to 1200 mg calcium per day would be adequate. Absorption of calcium through ingestion of dairy products is similar to that from a variety of calcium salt supplements. In the elderly, in whom an acidity may be a problem in terms of calcium absorption, supplements should be taken during meals.

Osteoporosis is the most common disease of bone and its incidence is increasing in many countries.



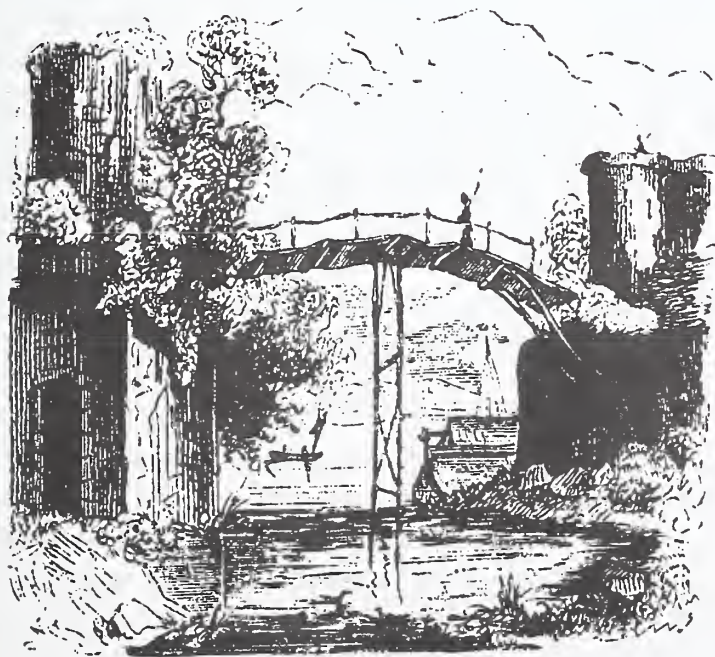
Weight-bearing physical activity is strongly encouraged. Patients are referred to physical therapy for instructions as to activities to avoid and for back-stretching exercises and exercises to strengthen the extensor muscles of the back. The patient needs to know that inactivity and lack of weight-bearing activities will have a negative impact on the skeleton.

Vitamin D plays a critical role in optimal skeletal and mineral homeostasis. With aging, there tends to be less vitamin D synthesis in the skin and dietary intake of vitamin D-fortified foods may be negligible leading to decreases in serum 25-OHD levels. Serum 25-OHD levels measure body stores of vitamin D and should be obtained in most patients, particularly the elderly. Up to 20% of elderly patients have

been reported with subclinical osteomalacia.¹² If serum 25-OHD levels are adequate (greater than 20ng/ml), a multivitamin with 400 units of vitamin D can be recommended on a daily basis to maintain those levels. However, patients with lower serum 25-OHD levels can take two multivitamin tablets (800 units of vitamin D daily) for several months to restore levels to normal. A second serum 25-OHD measurement can assess the adequacy of this supplementation.

Safe and effective agents are now available for the treatment of postmenopausal osteoporosis. In early postmenopausal women the goals are to prevent bone loss and reduce fracture risk. In those with osteoporosis, the goals are to stop or reverse bone loss, increase bone mass and reduce fracture risk. Many agents are currently under investigation for the prevention and therapy of osteoporosis. However, at present the only FDA-approved drugs are antiresorptive compounds which include calcium, estrogen, calcitonin, alendronate and raloxifene. Both estrogen and alendronate are approved for the prevention and treatment of osteoporosis. Calcitonin is approved for the therapy of osteoporosis in women who are at least five years postmenopause and raloxifene for the prevention of osteoporosis.

Appreciation of the protective effect of estrogen on the skeleton began with the observations of Albright and Reifenstein fifty years ago. Many studies now support the positive and protective effects of estrogen replacement on the skeleton.¹³ A variety of estrogen products including transdermal preparations have been shown to protect skeletal mass in peri- and postmenopausal women. In the United States, the greatest experience has been with the use of conjugated equine estrogen (Premarin). Recent studies have shown that estrogen therapy is also effective in conserving bone mass in the elderly who have been estrogen-deficient for many years.¹⁴ Increases in bone mass with estrogen therapy may explain most of the protective effect but there may well be other contributing factors. Epidemiological



studies are consistent with decreases of up to 60% in fracture risk at spine, forearm and hip for those who have received and continue to take estrogen for at least five to seven years. The effects of estrogen cease with its discontinuation and bone loss ensues once again. Any consideration of estrogen replacement therapy should include a discussion of other potential benefits, including prevention or alleviation of cognitive deficits, maintenance of dentition, cardiovascular protective effects through direct vascular and indirect effects on blood lipids, and maintenance of the vagina and pelvic floor. Some recent studies suggest a mild increased risk of breast cancer after prolonged estrogen therapy but many other studies have not found such a risk.¹⁵ The concern about breast cancer and other side effects such as uterine bleeding and breast tenderness has resulted in poor compliance with long-term therapy. For patients with a personal or strong family history of breast cancer, the risk of estrogen therapy may be unacceptable. Other contraindications to estrogen replacement include endometrial cancer, undiagnosed vaginal bleeding, severe active liver disease, and melanoma. Since unopposed estrogen therapy can result in endometrial hyperplasia and endometrial cancer, those with an intact uterus should also receive a progestational agent. The addition of a progestin eliminates such problems. Overall, the advantages of estrogen replacement therapy appear to far outweigh any potential disadvantages. This is reflected by data which demonstrate appreciable decreases in morbidity and mortality with long-term therapy.

Calcitonin slows bone remodeling rates and bone resorption through inhibition of osteoclastic activity. Calcitonin has not been shown to be effective in preserving bone mass in the perimenopausal or early postmenopausal years. Thus, parenteral and intranasal calcitonin preparations are recommended for women with established osteoporosis who are at least five years postmenopausal. Parenteral calcitonin is generally administered subcutaneously in doses of 50 to 100 units

daily. With parenteral calcitonin, some authors have shown increases in total body calcium over a twenty month period; others have shown increases in BMD at the spine, forearm and proximal femur. Generally, however, consistent increases are seen only at the lumbar spine and the effects are less than with estrogen or alendronate. Now that intranasal calcitonin is available, there is less interest in the parenteral preparation. Intranasal calcitonin in a dose of 200 units daily has a small positive effect on lumbar spine BMD with no measurable effect on forearm BMD. Alleviation of bone pain is often seen with both calcitonin preparations. Since, not uncommonly, continued therapy with calcitonin ultimately leads to a plateau response or escape phenomenon, some authors have suggested greater efficacy with intermittent therapy. Overall, the data indicate that calcitonin therapy is effective in preserving bone mass in those with postmenopausal osteoporosis. However, few studies document the efficacy of calcitonin therapy on fracture rates. In one prospective study, intranasal calcitonin therapy was associated with a decrease in vertebral deformities. In a two-year European retrospective study based on questionnaires, calcitonin therapy resulted in a 30% reduction in hip fracture risk.¹⁶ The protective effect of calcitonin was apparent after adjustment for calcium supplements and/or estrogen therapy. In a five year study of 11,075 postmenopausal women with osteoporosis, treatment with 200 units of intranasal calcitonin daily effected a 37% decrease in vertebral fractures despite the fact that lumbar spine BMD was not significantly different from placebo at three years. Calcitonin is relatively benign. Parenteral therapy is associated with nausea and flushing sensations in up to 20% of patients. With the intranasal preparation these adverse effects are less frequent but many patients experience rhinitis, nasal congestion and nasal irritation.

Bisphosphonates are pyrophosphate analogues in which a carbon atom has been substituted for oxygen.

These compounds are resistant to enzymatic activity and are potent inhibitors of osteoclast mediated bone resorption. Etidronate was the first of these compounds to be studied in patients with osteoporosis. Increases in lumbar spine BMD were documented with several years of cyclical therapy but because of questions relating to effects on fracture rates, the compound was not approved by the FDA for the treatment of osteoporosis. Two years ago, alendronate was approved for use in osteoporosis. In twin studies carried out in the United States and internationally involving almost 1,000 postmenopausal women, treatment with 10mg of alendronate daily was associated with significant increases in BMD at spine, proximal femur, and whole body.^{17,18} Importantly, these increases in BMD were associated with a 48% reduction in vertebral fracture rate. Subsequently, the Fracture Intervention Trial involving 2,027 postmenopausal women age 55 to 81 years with at least one vertebral fracture demonstrated similar decreases in vertebral, hip, and forearm fractures of at least 50%. In the Early Postmenopausal Intervention Cohort study involving 1609 women younger than age 60 and postmenopausal for at least six months, 5mg of alendronate daily prevented bone loss at the lumbar spine, hip and total body. Only at the forearm was there a greater effect of the estrogen progestin combination as compared with alendronate. As with all bisphosphonates, intestinal absorption is low, necessitating that it be taken in the fasting state with a full glass of plain water and no food or beverage other than water for at least 30 and preferably for at least 60 minutes. Patients should not lie down for at least 30 minutes after drug ingestion. Adverse effects with alendronate have been similar to those seen with placebo with the exception of a greater incidence of transient abdominal discomfort with alendronate.¹⁷ However, with general clinical use of alendronate, cases of erosive esophagitis have been reported. If patients with preexisting esophageal problems such as strictures and achalasia are excluded from treatment, there

should be relatively few adverse problems.

The FDA has just approved raloxifene for women who cannot or will not accept estrogen replacement therapy. Raloxifene is one of several nonsteroidal compounds, so called selective estrogen receptor modulators (SERMS) that have been under intense study. These compounds are similar to estrogen in their protective effect on the skeleton and possibly on the cardiovascular system. On the other hand, they do not stimulate breast or endometrium. In a two year study of 601 postmenopausal women 45-60 years of age and within two to eight years of menopause, treatment with raloxifene resulted in a decrease in bone turnover to premenopausal levels and increases in BMD at the spine, proximal femur and whole body of 1.2 to 1.6 % with differences of 2 to 2.4% between raloxifene and placebo-treated subjects.¹⁹ With raloxifene therapy total and LDL cholesterol levels decreased by 6.4% and 10%, respectively. Endometrial thickness did not increase. Safety data from more than 10,000 women indicate that raloxifene did not increase the risk of breast or endometrial cancer. These are exciting results but it is too early to comment about its potential in preventing osteoporotic fractures or coronary events.

SUMMARY

Osteoporosis is a potentially devastating disease affecting millions of Americans with more than 1.5 million fractures annually at a cost that is projected to be more than 60 billion dollars by the year 2020. Heightened patient awareness and education regarding risk factors, especially of behavioral and nutritional factors, should help in prevention particularly when directed to the young. The availability of precise measurements of BMD now facilitates the assessment of patients, the need for therapeutic intervention, and assessment of the response to therapy. The increasing number of approved, safe and effective therapeutic agents and the continuing intense research efforts bode well for improved skeletal health for women of all ages.

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Diagnosis and Treatment of Spinal Stenosis

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There is no more misunderstood degenerative disease of aging than lumbar spinal stenosis, and none more common. Recommendations for treatment are often anchored in the past, when the elderly were poor surgical candidates, anesthesia less sophisticated and surgery more destructive and primitive. But in the present, surgical treatment for spinal stenosis can offer the elderly patient increased ability to ambulate comfortably, a better quality of life, and prolongation of productive years. This paper discusses the pathophysiology, history and methods of surgical treatment, and outcome measures evaluating treatment success for lumbar spinal stenosis.

PATHOPHYSIOLOGY

As the body ages, the total water content decreases. Ask any elderly patient, who will tell you that, as the years have passed, his/her skin and hair have become noticeably drier. It is no surprise to find that the intervertebral disc, especially in the lumbar spine, loses its water content, decreases in height, and thus causes the relationship of the apophyseal (facet) joints to change. The

forces on the joint capsule then change, with instability at the affected segment. The surrounding tissues then lay down bone in the form of osteophytes anteriorly and around the facet joints laterally. In addition, the ligamentum flavum shows tremendous thickening posteriorly several times its normal caliber. These three forces cause a diminution of the size of the entire spinal canal with virtual obliteration of the neural foramina through which the segmental nerve must exit. (Figure 1)

PATIENT PRESENTATION

a) Acquired (secondary) Spinal Stenosis

The typical age of onset of symptoms is in the 5th and 6th decade of life. Practically all patients describe episodes of back pain with increasing intensity and decreasing pain-free intervals, in addition to numbness and radicular pain. Approximately 80% of patients will present with a feature that is almost diagnostic of spinal canal compromise: neurogenic claudication. Patients cannot walk even short distances without having to stop, sit, lie down or at least bend forward to re-

Abbreviations Used:

CT	computed tomography
MRI	magnetic resonance imaging

gain the ability to ambulate again for a short distance. With increasing activity, patients describe a painful numbness radiating into their legs from the buttocks down the thighs all the way into their feet and toes. Also, their legs may start to buckle. It is important to distinguish this form of claudication from the vascular type. While vascular intermittent claudication is caused by insufficient arterial blood supply to the crural musculature, the pathophysiological mechanism for neurogenic claudication is believed to be related to inappropriate neural discharges due to temporarily compromised blood supply to radicular nerves of the cauda equina. This restricted blood flow can also be provoked by standing or bending backward (hyperlordosis), which is therefore not well tolerated by patients with spinal stenosis. Bending forward or sitting down puts the lumbar spine into a flexion position where the posterior spinal elements move apart from each other, thereby releasing pressure on the neural elements and restoring adequate hemodynamics within minutes.

b) Congenital (Primary) Spinal Stenosis

Young patients in their thirties and forties may present with the same clinical picture, but with a different tempo. Where the elderly patient will report a gradual onset of symptoms over many months or years, the younger patient will give the history of a sudden onset of symptoms that sound identical to neurogenic claudication. An MRI will demonstrate a small spinal canal, but the features of osteoarthritis are absent. Instead, one sees shortened

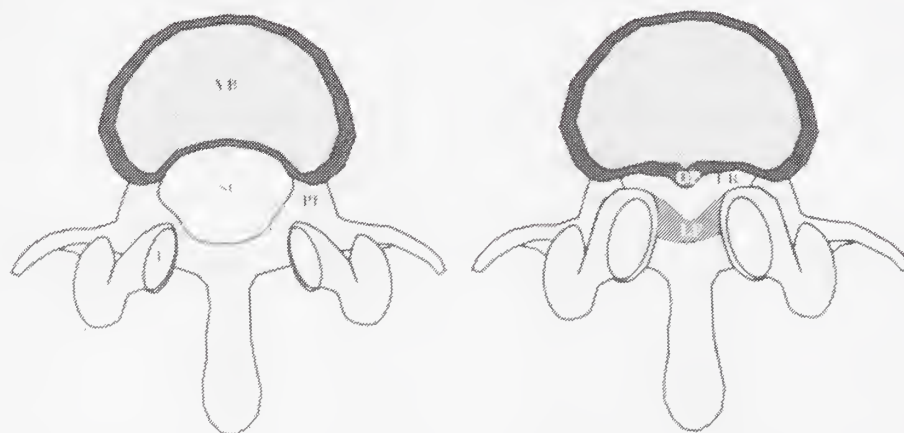


Figure 1. Schematic diagram of normal (left) and spondyloarthritic lumbar vertebra (right). Due to hypertrophy of the ligamentum flavum (LF) and the facet joints (F) the spinal canal (SC) and lateral recess (LR) are narrowed, resulting in compression of the cauda equina or the exiting nerve roots. VB = vertebral body, P = pedicle.

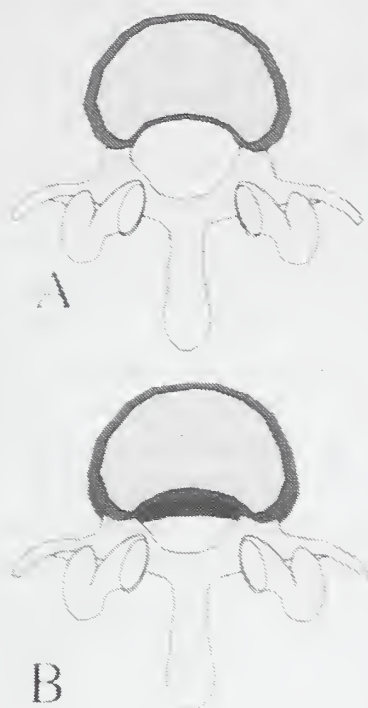


Figure 2. Primary congenital spinal stenosis, T2-weighted MRI, sagittal view. This young person had rather sudden onset of symptoms compatible with neurogenic claudication and was found to have pronounced congenital narrowing of the lower lumbar spinal canal. Note the presence of moderately sized disc bulges which, for a normal spinal canal, may remain asymptomatic but in this setting contribute significantly to spinal canal narrowing.

pedicles indicative of a congenital narrowing of the spinal canal from which the patient was previously quite asymptomatic. However, there is usually a modest disc bulge that causes an increase in the stenosis of the canal, and the patient becomes symptomatic. (Figure 2). Often the radiographic report is misleading - giving the physician the idea that there is only a small disc bulge in the context of a congenital spinal stenosis. It is therefore essential that the physician look at the film and not only at the report. In addition, the patient's symptoms should guide treatment.

c) Tandem Spinal Stenosis

It is essential that all patients who are being screened for lumbar spinal stenosis have a complete neuromusculoskeletal examination of all four extremities, and not just the lower limbs and back. Not only is this good clinical practice, but one often discovers signs of hyperreflexia and presence of pathological reflexes in the upper extremities, with depressed or normal reflexes in the lower extremities. This is usually a result of a similar osteoar-

thritic process in the cervical spine, with spinal canal narrowing and compression of the spinal cord. (Figure 3). Often the patient has very minor neck

pain with no radiculopathy and is surprised to be asked to undergo a cervical spine MRI prior to any surgical treatment for lumbar spinal stenosis. However, any cervical lesion of significance must be treated definitively prior to lumbar decompressive surgery. The rationale is that the positioning for the lumbar surgery can compromise the vascular supply of the cervical spinal cord by compression during the relatively long period of immobility during the surgery. Only when the cervical surgery has been carried out can the lumbar surgery be considered safe.

NEUROLOGICAL FINDINGS

On neurological examination patients with lumbar spinal stenosis may present with a variety of findings. About 50% of patients will complain of unilateral symptoms only. Commonly, radicular symptoms are described especially following the L5 and S1 distribution in addition to back pain. Strength is usually good and equal and reflex abnormalities may be limited to diminished or absent Achilles tendon jerks. Nerve root stretching tests such as the straight leg raising sign (Lasègue's sign) or reversed Lasègue's

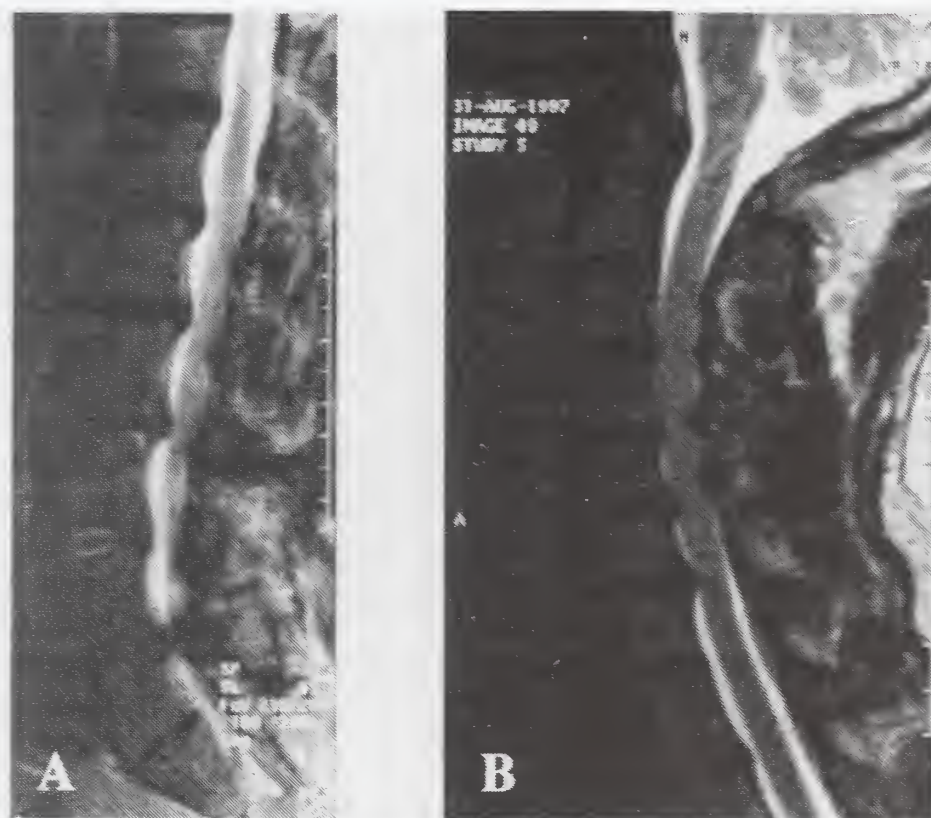


Figure 3. Tandem stenosis, T2-weighted MRI, sagittal view. The severe cervical spinal stenosis (B) resulted in myelopathy and required correction through a multilevel cervical laminectomy before the patient's more painful lumbar spinal stenosis (A) could be surgically addressed.

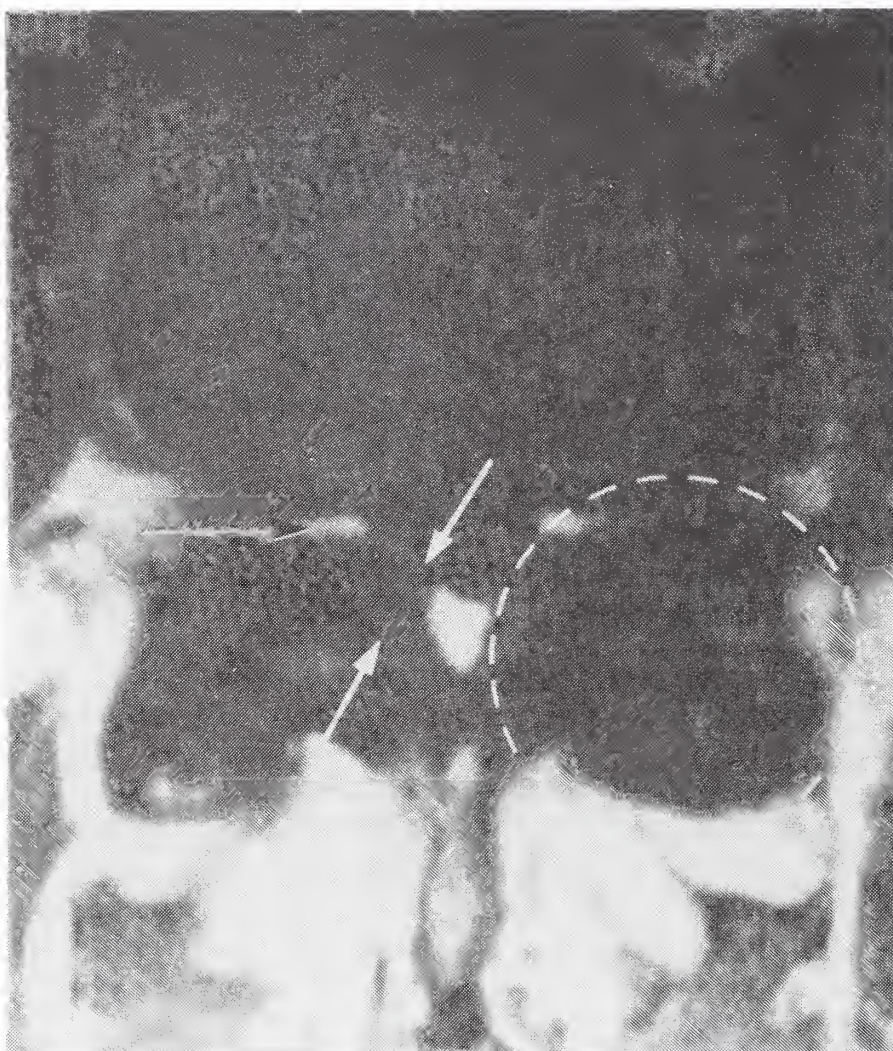


Figure 4. Spinal and foraminal stenosis, T2-weighted MRI, axial view. The white circle on the right indicates the severely enlarged facet joint complex which causes neural foraminal and lateral recess stenosis (black arrow, left). Osteophytes and severely thickened ligamentum flavum (two white arrows, left) contribute to narrowing of the spinal canal in the sagittal plane.

are typically negative. The neurological examination may be completely within normal limits even in the presence of severe lumbar spinal stenosis. In rare cases, lumbar spinal stenosis can lead to complete cauda equina syndrome when progressive symptoms of neurogenic claudication are disregarded.

IMAGING STUDIES

For a long time the myelogram, followed by a post-myelography computed tomography scan (myelo/CT), was considered the test of choice for the diagnosis of lumbar spinal stenosis. With rapid development of the quality of magnetic resonance imaging (MRI), this non-invasive diagnostic test has become as precise as the invasive myelogram in predicting the extent of the disease correctly in about

90% of patients.^{1,2}

Typical findings on MRI (Figure 4) show severe increase of the facet joint complex, resultant lateral recess syndrome and narrowing of the spinal canal due to osteophytosis and hypertrophy of the ligamentum flavum. In addition to the MRI, a plain non-contrast CT scan can also help depict the bony anatomy. It is not recommended as a sole test because of its inferior visualization of the soft tissues and its lack of precision for areas such as the thoraco-lumbar junction. Today, plain radiographs have no role in the diagnosis of lumbar spinal stenosis.

NON-SURGICAL TREATMENT FOR LUMBAR SPINAL STENOSIS

Most physicians tending the elderly would rather use as much non-sur-

gical (conservative) treatment as possible to alleviate their patients' symptoms. These measures include chiropractic, physical therapy with active muscle exercise or passive muscle relaxation, nerve blocks or epidural steroid injections. However, non-surgical measures which can have dramatic results in disc herniation usually have limited and only temporary effect on spinal stenosis.³ This is simply because none of these conservative means alters the underlying osteoarthritic pathology. The mechanical obstruction of the spinal canal is not reversible without surgical means; therefore, any non-surgical treatment offers only transient symptomatic relief without correcting or even addressing the cause of the misery.

HISTORY OF SURGICAL TREATMENT

The earliest description of the typical neurogenic claudication with a postural component is found in Sachs and Fraenkel's 1900 paper on an observation originally made in 1889.⁴ A surgical observation was actually reported earlier by Lane in 1893. His operative description anticipates that of every surgeon who attempts to help these unfortunate patients:

"On attempting to remove the lamina of the fifth lumbar vertebra, after cutting off its very prominent, largely developed and dense spinous process, it was found to be placed in the upper part of the sacral canal quite in front of its normal position. It was removed piecemeal with great difficulty. When the dura ...of the cauda equina of the right side was seen to have been so severely compressed as not to expand then the bone pressing on it was removed."⁵

Surgical treatment seeks to relieve the mechanical stenosis by enlarging the space for the cauda equina. The operative procedure is simple in concept, but sometimes difficult in implementation. The patient is placed in the prone position on a specialized frame that allows for easy access to the spine, and yet supports the chest and pelvis without compressing the abdomen. Care must be taken to prevent knee

pressure in patients who have had knee replacements or who are known to have symptomatic degenerative disease of the knees. A midline incision is made along the spine where the compression is, and a lateral shoot-through radiograph is taken to verify the operative level. The bony impingement is removed, including spinous processes, laminae, and medial facet joints. The neural foramen is enlarged by removal of bony and ligamentous structures encroaching upon it and the unimpeded egress of the nerve roots is visualized. An operating microscope can be utilized to ascertain the release of the nerve roots from any impingement.

Complications include rare events such as injury to the nerve roots, the cauda equina, or conus, producing new neurological deficits. These may or may not resolve, depending upon the nature and etiology of the injury. A moderately common event is the tearing of the dura mater which may be inordinately thin and adherent to the hypertrophied ligamentum flavum and facet joint overlying it. Although this is repaired at surgery and the patient usually experiences no ill effects, occasionally a leak of spinal fluid persists and the patient must be re-operated for treatment of a pseudomeningocele. Other uncommon side effects include post-operative hematoma compressing the cauda equina, and infection of the wound, which may produce an epidural abscess. Patients must be informed of these possibilities, but reassured that they are extremely rare.

Typically the patient is ambulating the day of surgery and home in a day or two. Physical therapy can be utilized on the first post-operative day to reassure patients about their abilities, and most report very little pain from the lumbar incision. Some patients are so de-conditioned by the time surgery occurs that they require placement in a short-term rehabilitation or nursing home facility before returning to their own homes. Most, however, can be discharged home, able to look after themselves, since their post-operative condition, even after surgery, is an improvement from their pre-operative status.

*...surgical treatment for
spinal stenosis can offer
the elderly patient
increased ability to
ambulate comfortably, a
better quality of life, and
prolongation of
productive years.*



OUTCOMES OF SURGICAL TREATMENT

Patients come to surgery for spinal stenosis because they have pain on ambulation or standing for any period of time. The pain is primarily in the buttocks and posterior thighs, unlike vascular claudication, which is usually in the calves. It stands to reason then, that outcome measures for successful therapy would center around demonstration of decreased pain and increased ambulation. Typically, the physician hears from the patient that she can now carry out activities of daily living more effectively and comfortably—mowing the lawn, doing the dishes, ironing the clothes—and can walk longer distances. Listing the activities and distances that were not possible previously, but which have become possible since surgical decompression, is the usual informal categorization of outcome. With payers and consumers' interest in medical outcomes, measures which previously would be seen only in clinical studies are finding their way into the

physician's office. These measures include *clinical measures* such as radiographic assessment of the decompressed canal, *functional measures* such as increase in treadmill walking distance, and *quality of life measures* such as a patient questionnaire, validated for health-related quality of life. Radiographic assessment in the form of a repeat MRI is usually reserved for those patients who do not have the desired outcome of surgery, not those who do, and it is therefore difficult to justify the expense for these studies when the patient is well. The treadmill test can be done pre- and post-operatively as part of the general assessment of the patient who may require re-conditioning for walking once the pain has been successfully treated. A patient-reported questionnaire can be performed as part of the initial assessment of the patient and measured again during follow-up. In the future, these data will be required as an integral part of quality assessment in practice.

Failure of the surgery to relieve the patient's symptoms must be investigated rigorously for causality. This usually means a repeat MRI to look for any residual compression. If such is found, re-operation must be offered to the patient. Most patients, no matter how uncomplicated their post-operative course, do not wish to be operated upon again, but many will proceed, believing that if it was worth undertaking once, it is worth undertaking again in the pursuit of a better quality of life. Most patients, after second surgery, will find the relief they were seek-

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ing and feel satisfied with the requirement for another operation. Fortunately, the second surgery is uncommon, because most patients respond very well to the decompressive procedure.

Occasionally, patients will do extremely well for some time following surgery: they have a new lease on life. However, months or years afterward, they may present with recurrent symptoms. Re-imaging is undertaken; and if the recurrence is within weeks or months of surgery, may show a disc herniation which was not present previously. If the recurrence is years later, a repeat MRI may show stenosis above the previously-treated levels of compression which was not present earlier. Again, re-operation can be undertaken for additional relief.

PATIENT APPROPRIATENESS AND EXPECTATIONS FOR SURGERY

The ideal surgical candidate for spinal stenosis treatment is a relatively healthy elderly person, active generally, ideal weight for height or only moderately overweight, with primarily leg pain on ambulation or standing for any period of time. However, this does not mean that a patient with hypertension or angina, or moderately obese, or with a relatively sedentary lifestyle should not be considered. Indeed, surgery has never been safer than at the present time, with sophisticated anesthetic agents and monitoring techniques, and brief surgical times in the hands of experts. Some patients are overweight because they cannot carry out the desired exercises or be active because of their pain. Most patients would appreciate the opportunity

for improved function and quality of life, regardless of other health problems. The surgeon is therefore dependent upon the primary care physician to advise regarding the medical risks engendered by surgery.

With respect to patients' expectations, it must be made clear that the most effective part of the treatment for lumbar spinal stenosis is the treatment of the buttock and/or leg pain which patients experience as the primary presenting complaint. The back pain which some patients have is only seldom diminished with surgery. This is because the surgery is directed at the compressive lesion which causes neurogenic claudication, and not at the entire spinal unit, other parts of which may be responsible for the patient's back pain. Most patients will declare that they can live with the back pain, but they find the radiating pain on ambulation and standing to be intolerable. It is therefore essential to discuss patients' expectations prior to undertaking any surgical treatment.

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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Corneal Arcus Senilis and Dyslipidemia

Philemon T. Marvell II, MD, and Robert S. Crausman, MD, MMS, FCCP

Corneal Arcus (Arcus Senilis, AS) is a commonly recognized physical finding in general medical practice that may be a clinical sign of an underlying dyslipidemia. Its pathogenesis is unknown but involves corneal deposition of cholesterol and phospholipid at the periphery of the stroma of the eye; thus, such an etiologic association would seem plausible. This issue has received little attention in the literature, and the available data are inconclusive.¹⁻⁸ While several studies have failed to demonstrate any association between arcus and dyslipidemia,^{3,6} others have yielded conflicting results.^{5,7,8} It therefore remains unclear whether or not the finding of AS has any significance in clinical practice.

METHODS AND RESULTS

A retrospective, case control study was performed to test the hypothesis that the physical finding of AS is associated with dyslipidemia. Eighteen patients with AS, visible without slit lamp examination, and a recent fasting lipid profile (within the four years of being identified for the study and prior to starting any antihyperlipidemic medications), enrolled in a hospital based internal medicine residency practice, were identified over a one year period (June 1995 to June 1996). Twenty control patients were randomly selected from the same practice. Excluded from the AS group were anyone who did not have arcus senilis, had no lipid profile or had no lipid profile prior to starting antihyperlipidemic medications. Con-

trol patients were excluded only if they had AS, or if they had not had a lipid profile in the four years prior to starting any antihyperlipidemic medication. All the lipid profiles i.e. total cholesterol, triglycerides and HDL cholesterol, were performed in a single hospital laboratory using a precipitation method on a Beckman CX-7 machine. The LDL cholesterol was calculated using the relationship $LDL\ cholesterol = total\ cholesterol - (HDL\ cholesterol + (Triglycerides/5))$. P val-

ues were derived using a single-tailed, two sample t-test. Results are expressed as the mean \pm the standard deviation.

Both groups of patients, those with AS and the controls, were similar (Table 1) with regard to age, gender, smoking status and history of comorbidity. The mean ages were 55 years \pm SD = 13 for the AS group and 52 yrs \pm 15 for the control group ($p=0.24$). There were 9/18 females in the arcus group and 8/20 females in the control group ($p=0.37$). The ar-

Table 1. Group Characteristics

	AS(n=18)	Control (n=20)	p value
Age (yrs)	55	52	0.24
Gender (M/F)	9/9	12/8	0.37
Smoking status	2	3	0.36
CAD	8	4	0.11
HTN	9	6	0.46
DM	2	2	0.27

AS = corneal arcus senilis, smoking status = ever, CAD = coronary artery disease, HTN = hypertension, DM = diabetes (type 1 or type 2)

Table 2. Mean composite serum lipoprotein values

	AS	St.dev.	Control	St.dev	p value
Cholesterol mg/dl	237	58	219	53	0.17
LDL mg/dl	157	55	149	48	0.34
HDL mg/dl	41	15	44	13	0.25
Triglycerides mg/dl	196	99	127	63	<0.01

LDL cholesterol = low density lipoprotein, HDL cholesterol = high density lipoprotein

cus group had 2/18 with a smoking history compared to 3/20 ($p=0.36$), 2/18 with diabetes mellitus compared to 2/20 ($p=0.27$), 9/18 with hypertension compared to 6/20 ($p=0.46$) and 8/18 with coronary artery disease compared to 4/20 ($p=0.11$). Comparison of the fasting lipid profiles (Table 2) showed a mean cholesterol of 237 mg/dl \pm 58 in the AS group and 219 mg/dl \pm 53 in the control group ($p=0.17$), a mean serum LDL of 157 mg/dl \pm 55 vs. 149 mg/dl \pm 48 ($p=0.34$) and a mean HDL of 41 mg/dl \pm 15 vs. 44 mg/dl \pm 13 ($p=0.25$). Triglycerides levels were significantly elevated in the AS group: a mean of 196 mg/dl \pm 99 vs. 127 mg/dl \pm 63 ($p<0.01$).

DISCUSSION

We demonstrated that AS identified by primary care physicians in the course of routine practice is associated with elevated fasting triglyceride levels, but not elevated total cholesterol and LDL nor reduced HDL in a group of older adults. This is consistent with data from the Lipid Research Clinics Program Prevalence Study, which demonstrated an association between AS and substantial elevations of triglycerides (157 mg/dl vs. 128 mg/dl $p<0.01$) in 20 to 49 year old men.⁵ The lack of association with other lipid levels here is in contrast with several other studies.^{2,5,8} Our findings suggest that corneal arcus senilis identified in general medical practice is a relevant marker for hypertriglyceridemia which may potentially prompt earlier recognition of this important dyslipidemia. Consequently, AS may be a clinical marker for increased risk of cardiac disease and could prove useful in prompting earlier detection of hypertriglyceridemia.

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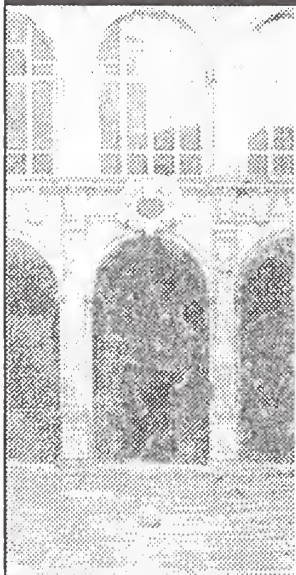
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Rhode Island Quality Partners, Inc.

Edward Westrick, MD, MS

Health Care Quality Improvement in Rhode Island: A Methodology (Part 2)

This column will continue last month's column on Health Care Quality Improvement Project Methodology. In last month's issue I covered the early phases in project development, including topic selection, collaborator recruitment, literature review, and development of consensus. Project Design deals with the issues of measurement, intervention, and evaluation.

The first issues in measurement deal with the indicators to be included in the project. Indicators can focus on processes or outcomes of care. Outcomes of care can include clinical outcomes, humanistic outcomes, or financial outcomes. Clinical outcomes are usually stated in terms of morbidity and mortality. Humanistic outcomes fall under the headings of functional status, quality of life, or patient satisfaction. Financial outcomes refer to the costs of providing care and the costs avoided through prevention.

Process indicators focus on practices that are associated with good outcomes. Simply put, quality in process means doing the right things well. Many have asked, "Who determines what the right things are?" For this answer we turn to the principles of Evidence Based Medicine (EBM). In last month's column I discussed EBM as it relates to topic selection. In a future edition of this column I shall go into greater depth on EBM.

Let me offer some examples of process and outcome indicators. In a Congestive Heart Failure project we will be looking at ACE inhibitor use and ejection fraction measurement as process measures, readmissions and quality of life as outcome measures. We tend to use more process measures than outcome measures because outcomes take longer to occur. For example, in an acute myocardial infarction (MI) project we are looking at a number of process indicators: thrombolytic therapy, aspirin, beta-blocker, and ACE inhibitor use. It is assumed that increasing beta-blocker use after MI will prevent deaths since we know of this relationship from multiple randomized controlled clinical trials. The increased use of beta blockers as a process can be measured in real time or within a short period of time, through chart abstraction. It will take a much longer

Abbreviations Used:

ACE	angiotensin converting enzyme
CDAC	Clinical Data Abstraction Centers
EBM	evidence based medicine
MI	myocardial infarction

period of time (a year or longer) to determine whether the outcome measure (mortality) has been affected.

Measurement development requires explicit specification of how the process or outcome is to be operationally defined. We must specify numerators, denominators, inclusion criteria, exclusion criteria, and the sources of data



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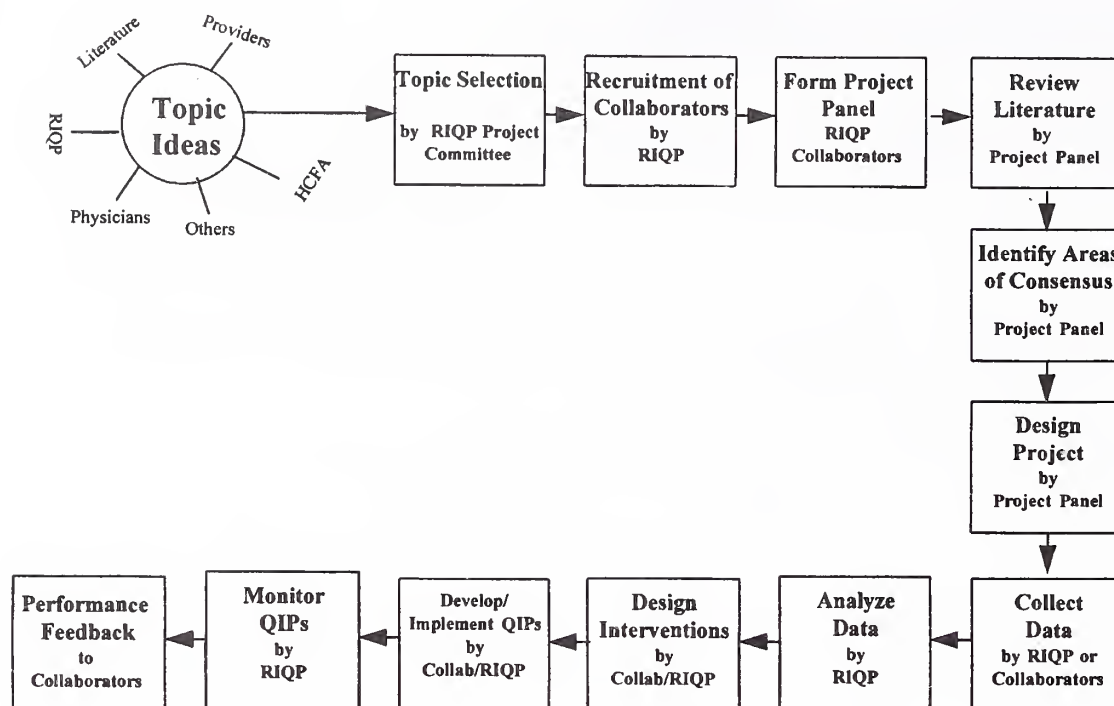
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HCQIP Project Methodology



for all of these elements. Issues of data reliability, validity, and cost of collection are considered during this phase. Our sources of data can include administrative databases, medical records, and surveys. The data sources vary with each project. In many of our projects we rely upon chart abstraction. Our acute myocardial infarction and pneumonia projects use data abstracted from hospital medical records. In other projects such as influenza immunization, early detection of breast cancer, and diabetic retinopathy prevention, we use Medicare Part B claims to measure the rate of immunization, mammography screening, and dilated fundusoscopic examinations, respectively.

The second major component of project design deals with interventions. RIQP works with collaborators and external partners to select interventions that will improve performance on the indicators when the analysis of baseline data detects that these opportunities exist. Interventions can include patient education, professional education, performance feedback, chart reminders, clinical pathways, and other management tools. When available, the interventions selected are based on prior evidence of their impact. External partners are not providers themselves. They, like us, are interested in improving health care in the topic area. They work with us on developing and delivering some of our interventions. The American Heart Association, RI Affiliate, the Diabetes Foundation of Rhode Island, Brown University, the University of Rhode Island, and the Rhode Island Department of Health have been some of our important external partners.

The third major component of project design deals with evaluation. We need to know how successful the projects are. We evaluate projects by their impact on the indicators, by their usefulness to our collaborators and

Medicare beneficiaries. For each project we state long-term, intermediate-term, and short-term goals. We measure our own performance in reaching these goals. Long-term goals can take years to achieve. Short-term goals are achievable in one project cycle. Our long-term goal in diabetes mellitus is to reduce microvascular and macrovascular complications of diabetes mellitus in Medicare beneficiaries. We will achieve this by offering a series of diabetes mellitus projects over the next few years. Our first project in this series focuses on diabetic retinopathy where our long-term goal is to reduce blind-

ness due to diabetic retinopathy. This outcome will take years to measure. The intermediate goal in this project is to detect diabetic retinopathy in its early stages. The short-term goal is to increase screening for diabetic retinopathy by eye care professionals.

Once the project design is complete we move into the data collection phase. For primary data collection, RIQP will either have its own trained abstractors collect the data locally or will use the services of the Clinical Data Abstraction Centers (CDACs), based in Maryland and Pennsylvania. These organizations employ experts in chart abstraction who enter data from charts into electronic databases. These data are analyzed by RIQP and the results are presented to our collaborators. Based upon the re-measured performance we will work together to redesign the project when there remain opportunities for improvement. To date, we have no projects that have completed the re-measurement phase. We anticipate this information during the summer and early fall.

I hope that this two-part series on project methodology has been helpful in explaining the science of health care quality improvement. I am happy to answer remaining questions. I invite others to contribute their work in health care quality improvement to this column. Please feel free to contact me at RIQP by phone (401) 528-3250, fax (401) 528-3210, or email ripro.ewestric@sdps.org.

Edward Westrick, MD, MS is the Principal Clinical Coordinator of Rhode Island Quality Partners. He is a member of the clinical faculty of Brown University School of Medicine and the Active Medical Staff of Roger Williams Medical Center. He is currently a PhD candidate at the University of Rhode Island studying Pharmacoepidemiology and Pharmacoeconomics.

RECENT ADVANCES In Laboratory Medicine

Advances in Breast Cancer Genetics

Hon Fong L. Mark, PhD, FACMG, Marlene McCarthy, and Donald Berry, PhD

This article is based in part on a conference held at the Rhode Island State House on October 6, 1997, under the joint sponsorships of the New England Regional Genetics Group (NERGG), Rhode Island Breast Cancer Coalition, and the Rhode Island Commission on Women.

In the three years since the Rhode Island legislature declared breast cancer an epidemic,¹ the awareness of breast cancer has increased, due mostly to the efforts of breast cancer advocates. Funding for breast cancer research has also become a national priority, again due mostly to the efforts of advocates. As a result there is renewed enthusiasm in the research on breast cancer genetics.

Breast cancer is one of the most serious diseases for women in the United States.² As a cause of death for women, breast cancer ranked second only to lung cancer. With the human genome project and major advances in the cloning of disease genes, clinicians suddenly confront a confusing multitude of possible laboratory tests. The complexity is further fueled by the issue of presymptomatic cancer genetic testing,^{3,4} as commercial companies aggressively market their products to increase their companies' share of predictive DNA testing. The present review summarizes the most recent advances in breast cancer genetics.

ESTABLISHED TECHNIQUES FOR CANCER GENETIC ANALYSES

Established techniques for cancer genetic analyses include conventional cytogenetics via banding, molecular techniques via fluorescent in situ hybridization (FISH) (Figure 1),⁵⁻⁹ and molecular biological techniques such as Southern blotting and PCR-based analyses. The study of the loss of heterozygosity (LOH), a molecular technique, has been used in the analyses of various cancers. [Oncogene amplifications, such as HER-2/neu, which can be studied using either molecular techniques or FISH, have been

Abbreviations Used:

CGH	comparative genomic hybridization
DNA	deoxyribose nucleic acid
FDA	Food & Drug Administration
FISH	fluorescent in situ hybridization
LOH	loss of heterozygosity
PCR	polymerase chain reaction
SKY	spectral karyotyping

an especially productive area of research.] Laboratory results are invaluable not only for diagnosing diseases, but for guiding clinicians through courses of therapy for their patients. An example is the interaction between dose/schedule of chemotherapy (cyclophosphamide, doxorubicin, and 5-fluorouracil) and HER-2/new (assessed by immunohistochemistry and also gene amplification using polymerase

chain reaction). It was found that patients with HER-2/neu negative tumors survived equally well on all three dose regimens.^{10,11} The clinical implication of this observation is profound. It suggests that patients with HER-2/neu-negative tumors do not benefit from higher doses of this particular chemotherapeutic combination; perhaps a different chemotherapy regimen would be more appropriate. Moreover, this interaction seems to be even stronger when considering p53 positivity.¹¹

NEW EVOLVING CYTOGENETIC TECHNOLOGIES

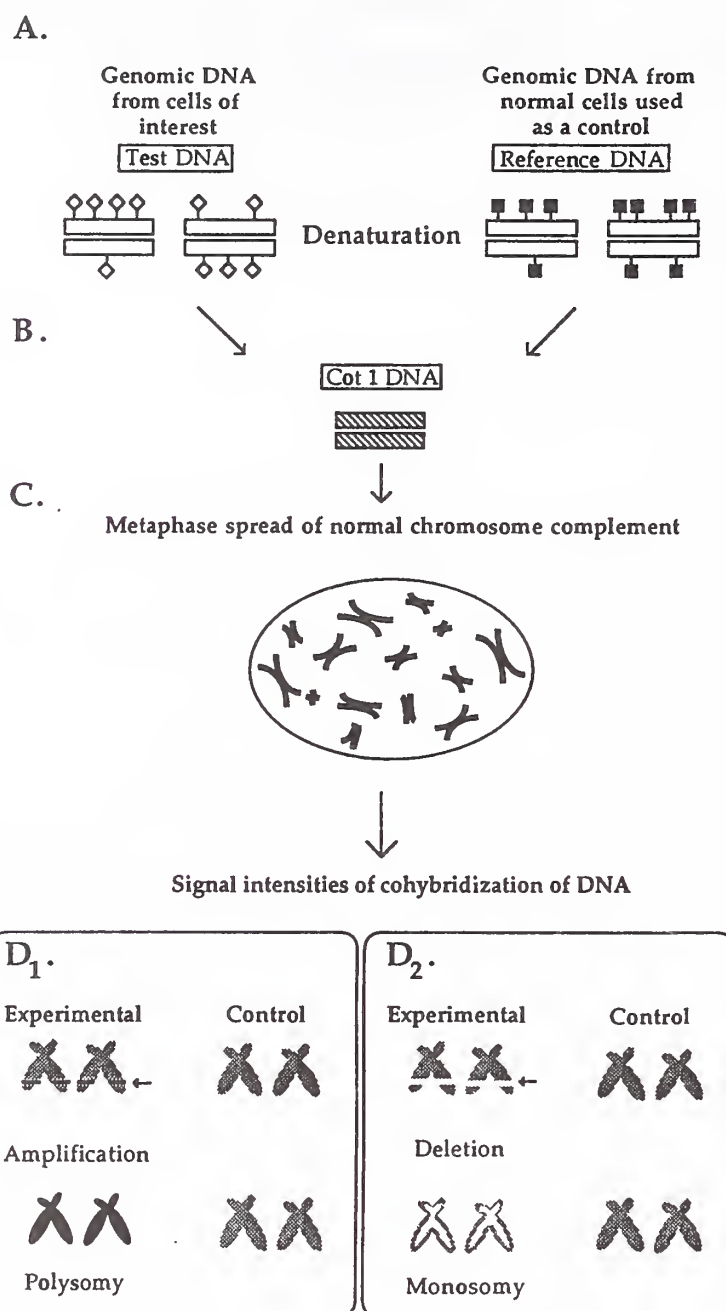
During the last several years, the field of molecular cytogenetics has experienced a technological revolution with the development of two new techniques: comparative genomic hybridization (CGH)¹²⁻¹⁴ and spectral karyotyping (SKY).¹⁵⁻¹⁷ The latter is a special methodology for multi-color FISH.

CGH allows for the identification of

*...because today's
"research" is tomorrow's
"clinical service," it
behooves all physicians,
scientists, and other
interested parties to
closely monitor the
emerging issues in this
constantly evolving field
which will
unquestionably touch the
lives of many of our
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Figure 1.
Comparative genomic hybridization (CGH)



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DNA sequence copy number changes in solid tumors and enables a map of gains and losses of chromosomal material to be produced with respect to size, frequency, number, location and effect on the entire genome. SKY, on the other hand, permits the distinct visualization of each chromosome in a single display by labeling with a rainbow of fluorochromes.¹⁸

Although FISH-based, both technologies have unique characteristics which may prove to be superior to conventional FISH techniques. Whereas FISH requires prior knowledge of the specimen in order to select the correct probe for either metaphase or interphase analyses, CGH (Figure 2) only requires the availability of genomic DNA for analysis. Additionally, SKY can recognize small cryptic translocations more readily than FISH. Given that each chromosome is assigned a unique painting color, a translocated DNA sequence can be instantly visualized by the in-

roduction of a segment with a foreign color. Unlike CGH, SKY has the added feature of being able to identify balanced chromosomal rearrangements that show no gains or losses in sequence copy numbers.

CGH and SKY are new techniques that need additional refinements. Only a few specialized centers with adequate resources to train and support research personnel can routinely perform these techniques. In addition, they require expensive instrumentation, such as digital imaging equipment which in this age of managed care and corporate down-sizing,¹⁹ may not be practical in many settings. Furthermore, because of their relative novelty, issues in connection with testing, such as sensitivity and specificity, are not yet well-defined. Thus, caution should be exercised when interpreting CGH and SKY results. These same considerations should apply to many FISH-based tests using probes that are not FDA-approved.

PREDICTIVE DNA TESTING OF BREAST CANCER GENES

The first breast cancer gene was localized to human chromosome 17q21 using genetic linkage analysis in families with a high incidence of early-onset breast cancer.²⁰ This pioneer work formed the basis for the isolation of the BRCA1 gene²¹ and subsequent advances in research on the BRCA2 gene.²² It has been estimated that 5 to 10% of breast cancer and ovarian cancer cases occur as part of heritable syndromes. These cases are the natural target for close monitoring by physicians.

In the past few years, commercial testing for mutations of the BRCA1 and BRCA2 genes has become available. Two companies offer these tests to the public, with one charging \$2400 for testing both genes.

The potential benefits of predictive tests may be overshadowed by misunderstanding. In particular, whether or not they have a family history of breast cancer, women tend to overestimate the risk of breast cancer and of carrying a susceptibility gene mutation. In addition, there is potential for economic discrimination by employers and insurers.²³


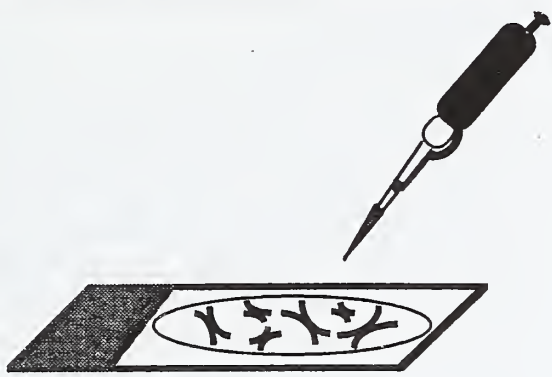
Because of the concerns surrounding cancer genetic testing, Li et al.²⁴ suggested that predictive testing and counseling should be conducted in a research setting and should involve experts in oncology, psychiatry, genetic counseling, medical ethics and medical and molecular genetics.

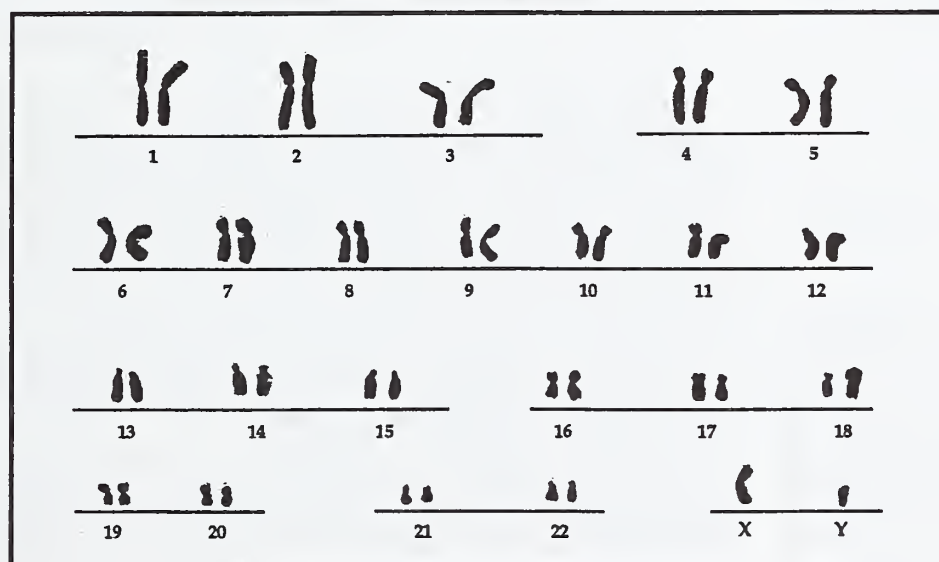
The legal, ethical and social issues involved in screening and testing for cancer predisposition genes are complex. Individuals must be carefully counseled regarding the potential psychological outcome and other impacts of predictive DNA test results.⁴

Accurately identifying a woman's risk of breast cancer is important and researchers have constructed predictive

Figure 2.

Spectral karyotyping (SKY)

- A.** Preparation of metaphase spreads
- 
- B.** Labeling of probes and hybridization to the chromosomes
- 
- C.** Spectral imaging and production of a rainbow-colored karyotype whereby each chromosome can be distinguished by a different color



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models. For example, Gail et al.²⁵ developed a method to estimate the chance that a woman at a given age, with a particular set of risk factors, will develop breast cancer over a specified period of time. However, this model does not adequately incorporate a family history of breast and ovarian cancer. Berry et al.²⁶ and Parmigiani et al.²⁷ developed an alternate model for assessing a woman's risk of carrying a mutation of BRCA1 or BRCA2 and of developing breast cancer over a specified period of time.

CONCLUDING COMMENTS

As biotechnology companies and university-based researchers establish laboratories for the analysis of cancer predisposition genes, high standards are essential in the genetic testing laboratory, including qualified personnel and

strict compliance with established regulations.²⁸⁻³⁰

Aside from support structures, such as genetic counseling and social services, which must be made available outside the laboratory, quality assurance and quality control measures must also be established within the laboratory. In addition, because today's "research" is tomorrow's "clinical service," it behooves all physicians, scientists, and other interested parties to closely monitor the emerging issues in this constantly evolving field which will unquestionably touch the lives of many of our patients.

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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Prevalence of Arthritis in Rhode Island, 1996

Tara A. Breslosky, MPH, and David E. Hamel, MPA

Arthritis is a major cause of activity limitation in the United States. National estimates indicate that arthritis is the most commonly reported chronic condition of persons over the age of 18, increasing markedly in prevalence after age 45.¹ In addition, population projections predict that both the number and the proportion of persons aged 65 and older will rise sharply nationally and in Rhode Island, which will increase the prevalence of arthritis.

Methods

Since 1984, the Rhode Island Department of Health has conducted the Behavioral Risk Factor Surveillance System (BRFSS), an ongoing, random digit-dial, statewide telephone survey of adult residents. The BRFSS is currently conducted in all states as a cooperative effort between the national Centers for Disease Control and Prevention and state health departments. In 1996, the Department, working with a contractor, conducted telephone interviews with 2,482 adults in the state. A module of questions on arthritis, funded by the Department of Health's Disability and Health Program, was included in the BRFSS to estimate the self-reported prevalence of clinically diagnosed arthritis.

The six questions in the module address the prevalence of chronic joint problems and include questions specific to an arthritis diagnosis. (Table 1)

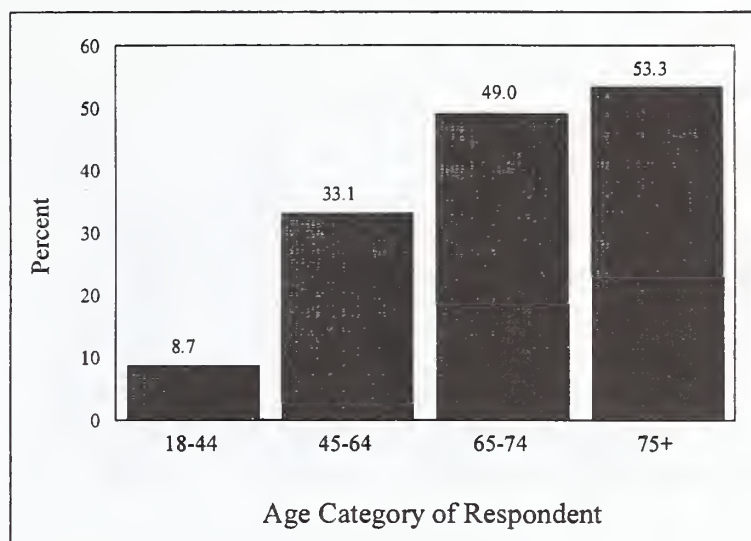


Figure 1. Prevalence of arthritis among Rhode Island adults, by age group, 1996.

Results

Nearly 38% of respondents reported experiencing pain, aching, stiffness, or swelling in their joints at some time during the previous twelve months. Of respondents who reported joint symptoms, more than 30% were limited in their activities as a result of these problems.

For the purpose of this report, persons who said they had been told by their doctor they had arthritis were considered to have arthritis. Although almost 38% of respondents experienced chronic joint problems, a smaller percentage reported a doctor's diagnosis of arthritis. Based on 1996 BRFSS results, prevalence rates of arthritis are 23.2% in Rhode Island. Among Rhode Islanders with an arthritis diagnosis, more than 37% said they were limited in their activities as a result of their condition.

The prevalence of arthritis, like most disabilities, increased with age. (Figure 1) More than half of the respondents age of 75 or older reported a diagnosis of arthritis. Age-specific prevalence rates were uniformly higher for women. (Figure 2) Reasons for higher rates of arthritis among women are not well-established; however, some studies suggest a strong

Table 1

Prevalence of Chronic Joint Problems

"During the past 12 months, have you had pain, aching, stiffness or swelling in or around a joint?"
"Were these symptoms present on most days for at least one month?"
Are you now limited in any way in any activities because of joint symptoms?"

Self-reported Arthritis Diagnosis

"Have you ever been told by a doctor that you have arthritis?"

Type of Diagnosis

"What type of arthritis did the doctor say you have?"

Treatment of Arthritis

"Are you currently being treated by a doctor for arthritis?"

Questions on the arthritis module of the 1996 Rhode Island Behavioral Risk Factor Surveillance System.

Table 2	
Type of Arthritis	Percent
Osteoarthritis	27.3
Rheumatism	3.0
Rheumatoid Arthritis	8.9
Lyme Disease	0.6
Other	4.8
Refused	0.2
Don't know type	55.2

Type of arthritis reported by Rhode Island adults with arthritis, 1996.

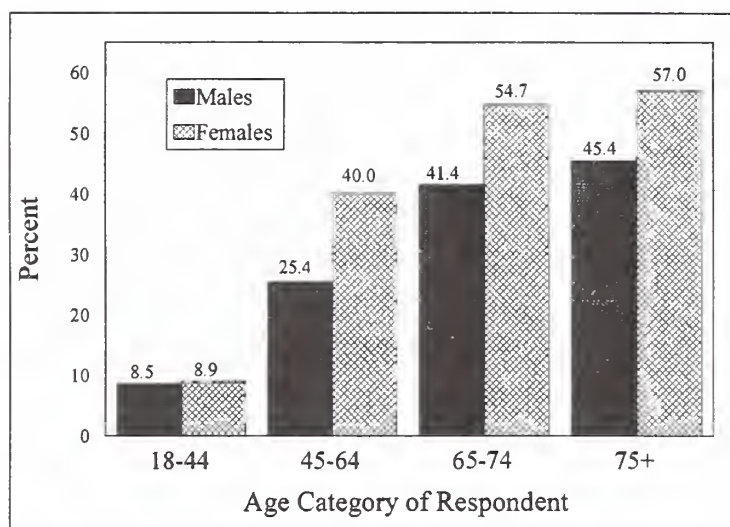


Figure 2. Prevalence of arthritis among Rhode Island adults, by age group and sex, 1996.

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correlation between menopausal status and arthritis, more specifically, osteoarthritis.^{2,3} The effect of the depletion of female sex hormones on cartilage may prove to be a factor in the increased risk of arthritis for post-menopausal women.

Of those individuals who were told by a physician that they had arthritis, 55.2% did not know the type of arthritis. (Table 2) Of those with an arthritis diagnosis, 31.9% were currently being treated by a doctor for arthritis.

Discussion

The Rhode Island Disability and Health Program (DHP), which is funded by a cooperative agreement with the Centers for Disease Control and Prevention, recognizes the importance of population-based surveillance for limitations and disabilities. The data collected on the BRFSS have provided arthritis programs with self-reported prevalence rates for this condition for the state and have allowed for identification of high-risk groups in the population. Accordingly, the DHP plans to fund this module in subsequent years to monitor the impact of arthritis in Rhode Island, to describe the affected population, and to otherwise support arthritis prevention and treatment efforts. In addition, the findings presented here indicate a need for medical and behavioral interventions, along with education about arthritis and available treatments. Educating patients on pain management and instituting muscle strengthening exercises are often beneficial therapies. Interventions that promote primary prevention of arthritis include avoiding joint trauma, weight reduction measures, and implementing ergonomic modifications in the workplace.⁴

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Proposed Goals for Cancer Prevention

John P. Fulton, PhD

Objective

The Rhode Island Department of Health assembled an Expert Panel on Cancer Prevention to advise the Department on revising the State's current cancer control plan, published in 1989.¹ After reviewing the current approaches to cancer prevention recommended by national organizations and the most recent pertinent literature, the Panel proposed goals for cancer prevention to be incorporated in a revised cancer control plan for the State.

Methods

- Review current approaches to cancer prevention recommended by national organizations.
- Review the most recent literature pertinent to cancer prevention.
- Discuss.
- Propose goals for cancer prevention.
- Write a simple rationale for the proposed goals.
- Invite comments on the proposed goals and rationale.

Proposed Goals

- Avoid tobacco.
- Avoid environmental tobacco smoke.
- Avoid excessive sun exposure.
- Eat a balanced diet.
- Get regular physical activity.
- Avoid exposure to cancer-causing substances in the workplace.
- Avoid exposure to cancer-causing substances in the home and leisure settings.

Rationale for Proposed Goals

The proposed goals for cancer prevention were selected to reduce exposure to known determinants or correlates of cancer which are common and avoidable. The rationale was developed largely from three documents: Cancer Rates

and Risks; Guide to Clinical Preventive Services, 2nd ed.; and Healthy People 2000. National Health Promotion and Disease Prevention Objectives.²⁻⁴

Tobacco use is the single most important cause of cancer in the United States. Between 20 and 25% of adults use tobacco. Tobacco use is entirely avoidable. Children get seduced into using tobacco products by unscrupulous marketing practices, become strongly addicted to nicotine, and may take many years to quit. Preventing tobacco use by children is an extremely effective means of reducing tobacco use overall, because it is a habit rarely initiated by adults.

Creating disincentives for tobacco use and helping tobacco users quit have been shown to be useful in reducing tobacco use, as well.

Exposure to environmental tobacco smoke (ETS) is a significant cause of lung cancers in people who themselves do not use tobacco. Between 3000 and 6000 lung cancer deaths per year in the United States are caused by exposure to ETS. A substantial proportion (perhaps a majority) of the population in the United States have some exposure to ETS in the home, at work, or in public settings such as restaurants. Those who live with smokers, and those who work in smoky environments, such as bars or restaurants that permit smoking, may have dangerous exposures to ETS. Recent experience has shown that exposure to ETS may be reduced by the development of state, local, and organizational policies which restrict or ban indoor smoking, and by educating the public to avoid ETS.

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Excessive sun exposure is the most important cause of skin cancer, including melanoma of the skin, in the United States. Exposure to the artificial ultraviolet light emitted by commercial tanning booths, sun lamps, and other sources, may also cause skin cancer. Basal and squamous carcinoma of the skin, especially of the face, scalp, and neck, are very common in the United States. Melanoma of the skin is a very serious disease with a high case fatality rate, and is on the rise in the United States. Almost all individuals are exposed to sunlight, but in almost all cases, excessive exposure may be avoided by wearing protective clothing. In those cases where protective clothing cannot be worn, or may not be worn reliably, as with children, the use of sunscreen is prudent, even though the effectiveness of sunscreens in preventing skin cancers has not been proven.

A diet high in fat and low in fiber is believed to be the primary exogenous cause of colo-rectal cancer, and is related to other common cancers, as well. In the developing world, where diets are largely based on grains, vegetables, and fruits, and have a low fat content, colo-rectal cancer is far less common than in the developed world, where meat, whole milk, eggs, oils, and spreads based on fats or oils represent significant sources of calories. Although diets are difficult to change, the typical American diet has changed over the past decades in response to information and promotional campaigns. As a result, for example, the consumption of sodium is down, and the proportional consumption of reduced-fat meat and dairy products is up.

Heavy consumption of alcohol is associated with cancers of the mouth, pharynx, larynx, esophagus, liver, and breast. Heavy alcohol consumption and smoking have long been known to have a synergistic effect on cancers of the mouth, pharynx, larynx, and esophagus. Between 5 and 10% of the adult population in the United States consume alcohol at levels that clearly put them at increased risk of cancer, and a higher proportion consume alcohol at levels that may put them at some increased risk. Problem drinking may be prevented by education and counseling and treated effectively by counseling and medical intervention.

A sedentary lifestyle is associated with colo-rectal cancer. Between 50 and 60% of the adult population in the United States do not engage in regular physical exercise, putting them at increased risk of colo-rectal cancer, as well as other significant diseases and conditions. Regular, moderate physical activity such as walking for about 30 minutes a day may decrease the risk of cancer and other chronic illnesses significantly. Such exercise is readily accessible to the population at large, and modest health promotion efforts have been demonstrated to increase physical activity.

Certain industrial processes have been strongly linked to cancers of the lung, bladder, nasal cavity and sinuses, larynx, pharynx, lymphatic and hematopoietic system, skin, and liver, and to mesothelioma. The proportion of the population at risk of exposure to cancer-causing materials in the workplace changes over time, as new industrial processes are invented, and old processes become outmoded.

Nonetheless, industrial processes are believed to cause at least 5% of all cancers, and some estimates of this proportion are considerably higher. Because industrial processes occur in well-understood, organized, and well-monitored environments, subject to federal and state laws regarding the protection of workers and the safe handling of unsafe materials, almost all dangerous exposures to cancer-causing substances may be minimized or avoided altogether by properly designing the work environment, by carefully selecting the materials for use in that environment, by providing workers with protective clothing and gear, by educating workers about the safe handling of unsafe materials, and by monitoring the entire system of protection thus implemented.

Significant exposure to radon (lung cancer) and asbestos (mesothelioma) may occur in the home setting. Homes, especially newer homes, have been built to retain heat, and thus restrict air exchange between inside and outside environments. Therefore, once in a home environment, cancer-causing substances tend to be retained. Unacceptable levels of environmental radon and asbestos may be detected in homes using simple tests and inspections, and the cost of removing or controlling either substance in most affected homes is usually not prohibitive. The control of these substances in the home is amenable to public education, regulation regarding the sale of homes, and subsidies for removal or control. Other cancer-causing substances such as pesticides and gasoline may be used improperly in the home or leisure settings, causing significant, unsafe exposures. The control of these substances in the home is simple, inexpensive, and amenable to public education.

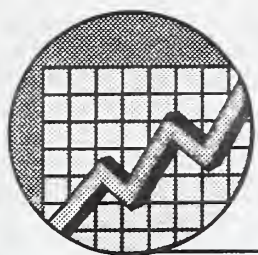
Comments?

We invite your comments on the proposed goals and rationale. Please send them in writing to Dr. John Fulton, column editor, either by fax (401-861-5751) or mail (Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097).

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events

	Reporting Period		
	November 1997	12 Months Ending with November 1997	
	Number	Number	Rates
Live Births	1,201	13,438	13.6*
Deaths	883	10,036	10.1*
Infant Deaths	(8)	(93)	6.9#
Neonatal deaths	(6)	(77)	5.7#
Marriages	521	8,124	8.2*
Divorces	314	3,125	3.2*
Induced Terminations	413	5,534	411.8#
Spontaneous Fetal Deaths	134	1,023	76.1#
Under 20 weeks gestation	(130)	(945)	70.3#
20+ weeks gestation	(4)	(78)	5.8#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death

	Reporting Period			
	May 1997	12 Months Ending with May 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	279	3,405	343.9	4,051.0**
Malignant Neoplasms	206	2,476	250.0	6,577.5
Cerebrovascular Diseases	62	620	62.6	937.0
Injuries (Accident/Suicide/Homicide)	27	342	34.5	6,024.0
COPD	33	457	46.2	290.0**

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

THE RHODE ISLAND MEDICAL JOURNAL

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NINETY YEARS AGO

[MAY, 1908]

In the lead article Franklin C. Clark, MD, discusses malpositions of the ulnar bone in Colles' fractures. The author refers, specifically, to the "dropping or deviation of the ulna from its proper relations; and this with or without its dislocation in the initial injury." Most texts on the treatment of Colles' fractures, the author contends, generally ignore this untoward orthopedic event. The author presents the histories in two cases. The first is a 40 year old woman who had fallen down a partial flight of stairs. The fracture was reduced in the patient's home; and on multiple subsequent home visits, the splint was readjusted in an unsuccessful attempt to reduce the swelling and to undo the deviation of the fractured ulna but to no avail. The second case was a 60 year old woman who had also fallen, fracturing her radius. In both cases the wrist became useless despite union of the fractured radius. Nowhere in the meticulous description of these two cases was there mention of taking an X-ray of the wrist.

S. Newell Smith, Jr, MD, discusses the treatment of fractures of the upper extremity, largely because, in his experience, it comprises a large proportion of a surgeon's work during the winter. He first considers fractures of the clavicle and the various kinds of reductive maneuvers as well as splints to be employed. He then summarizes fractures of the humerus [involving the humerus head, the anatomical neck, epiphyseal separation or the surgical neck.] He further considers fractures of the olecranon, the radius [midshaft] and Colles' fractures. He concludes with a brief discussion of compound fractures and their therapy.

Coloproctitis is considered by V. Lee Fitzgerald, MD. Within this diagnostic category are included such entities as mucous colitis, colonic dyspepsia or diarrhea associated with mucous evacuations, colicky pain, anemia and "a neurotic diathesis." The author considers the various diagnostic components of the disease, its pathophysiology and nonsurgical treatments [eg, nux vomica, sodium benzoate, bismuth salicylate], abdominal massage and dietary modifications.

TWENTY FIVE YEARS AGO

[MAY, 1973]

The Presidential Address delivered by Robert V. Lewis, MD, at the 162nd Annual Scientific Assembly of the Rhode Island Medical Society is entitled, "Rhode Island Physicians' Attitudes on the Present and Future Practice of Medicine." The presentation summarizes a careful survey of the practicing physicians undertaken by the author. He concludes on an optimistic note, describing his colleagues as "not averse to change; ... will-

FIFTY YEARS AGO

[MAY, 1948]

F.A. Simeone, MD, summarizes the use of blood and plasma in surgical emergencies, noting that these are indispensable agents for restoring the circulating blood volume. He then considers the role of whole blood in the pathodynamics of traumatic shock. The author next explores the role of plasma in cases of extensive burns and the importance of determining total fluid loss in the rational management of such cases.

Robert T. Henry, MD, discusses fractures of the shaft of the tibia particularly since such fractures are so often associated with compounding and secondary infection. He emphasizes the need to remember that tibial fractures have a tendency for poor alignment or pathological rotation of the fracture ends leading to poor union and painful walking.

A case of subacute bacterial endocarditis, successfully treated with penicillin, is presented by Jacob Greenstein, MD. The patient was a 27 year old woman with no known history of rheumatic fever. The current illness commenced with chills and fever. There was clinical evidence of a mitral insufficiency. Blood cultures were positive for *Streptococcus viridans*. Parenteral penicillin [20,000 units every four hours for 16 days] temporarily controlled the infection, but a few months later the signs all recurred despite further courses of penicillin. Finally a massive dosage of penicillin was used with total recovery.

The lead editorial discusses the role of the Crawford Allen Hospital in the rehabilitative care of children with rheumatic fever and its sequelae.

The new President of the Rhode Island Medical Society is Joseph C. O'Connell, MD; the President-Elect is Peter Pineo Chase, MD.

ing to change records and record keeping; and... willing to make his records available. He is willing to enter into a capitation group in which there is reasonable equity of distribution and professional control." He ends: "We have reestablished our identity."

Arnold Porter, MD, considers Blue Shield, National Health Insurance and government's role in protecting the public interest, particularly in setting uniform standards of excellence.

The principal editorial discusses the problems and progress in childhood immunizations.



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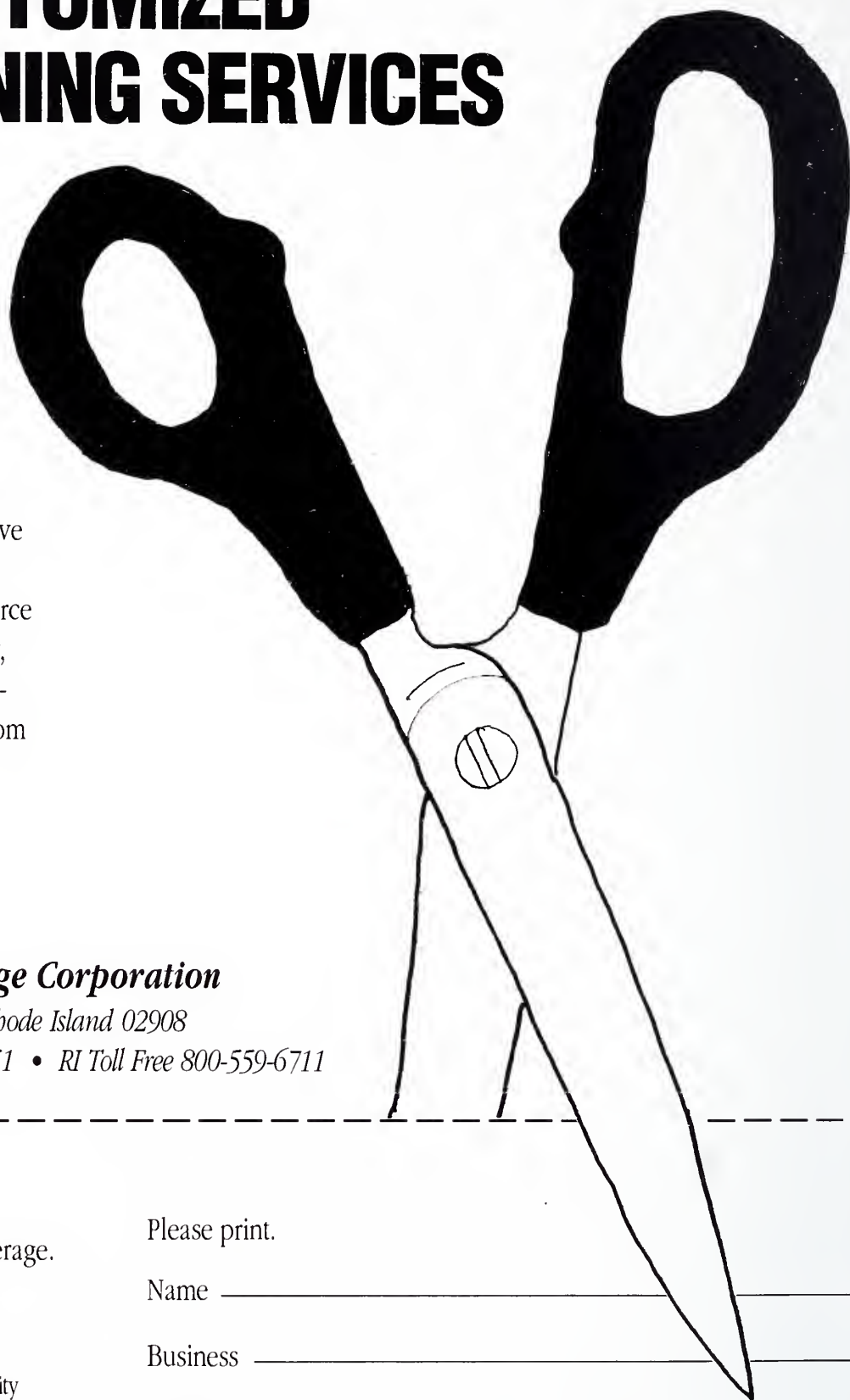
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COMMENTARIES

When the Time for Heroics Has Passed

"Many have studied to exasperate the ways of Death, but fewer hours have been spent to soften that necessity."

— Sir Thomas Browne

Physicians have never quite known how to behave at the bedside of their dying patients. It may even have been harder 30 years ago before our amazing life-extending [or dying-extending] technologies were available to keep us busy. I knew a distinguished endocrinologist who, when his patient took her last breath as he stood by, seemed embarrassed, crossed himself, bowed slightly, and backed out of the room. Sometimes in those far off days we would call for an epinephrin-filled syringe with a long needle and aim it at the precordium, empty it, and wait. In my experience nothing ever happened, but we could leave feeling that we had done our best.

Now hospital deaths are often wild, a confusion of unfeeling, but well-meaning, noisy busyness in the ICU, nurses and housestaff standing by or manipulating tubes, defibrillators, respirators, or just watching the monitor as someone forcibly and rhythmically compresses the chest. Hardly the euthanasia, the peaceful departure, the good death that the ancients wished for themselves and their families. Daniel Callahan wrote of the "wild death," earlier described by Philippe Aries, and now so common in our hospitals:

"It is wild not simply because it is out of control and terrorizing in its modern incarnation, but also because, in the name of combatting mortality, it has managed simultaneously to subvert the institution of medicine, which cannot overcome mortality, and the mortality of decisions about life and

death, which should not have to bear the responsibility of omni-responsibility."¹

Callahan hardly intended to deny anyone the right to choose the wild death, "... technical brinkmanship without restraint, aiming to go as far as medical aggressiveness will allow," but that he should know and be prepared to accept "risking a terrible death - a risk for himself but also for those who care for him."²

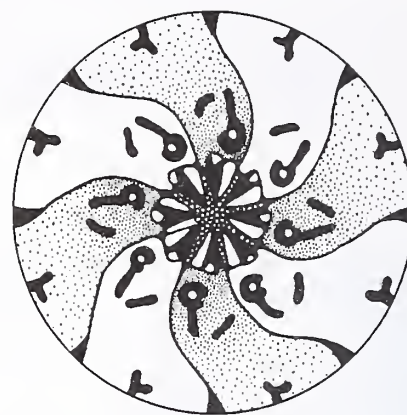
In discussions with older men and women, those mostly well beyond the Psalmist's three score and ten, I have found an almost universal fear - even terror - that instead of that peaceful death that nature so often provides, they will be pummeled by EMTs, delivered to the ER, and then rolled away to the ICU with absolutely no choice in the matter, and spouses or children powerless, or not aggressive enough to intercede. Over and over I hear of living wills ignored, especially when they could not be produced on the spot. One elderly man thought he might have DNR tattooed on his forehead! More than this, many are concerned that in the helplessness of their final illness they will be subtly urged by well-meaning families and physicians to have just one more round of chemotherapy or radiation, or will be cheated out of a quiet death from pneumonia. I recall a wife and her two sons, both ministers, blocking the hospital room doorway of her husband and their father, near death from leukemia, for whose pneumonia a resident had, not inappropriately, ordered antibiotics to be given. They won the standoff, but only because they were able to reach the patient's physician and friend by phone. The patient died a peaceful death 24 hours later, and the resident

sulked.

Leon Kass writes that our urge to medicalize death is *hubris* and reminds us of the tragic fate awaiting those who succumb to this all-too-human fault. "We do not understand that the project for the conquest of death leads only to dehumanization, that any attempt to gain the tree of life by means of the tree of knowledge leads inevitably to the hemlock ..." and that "the victors live long enough to finish life demented and without choice." He concludes:

"The present crisis that leads some to press for active euthanasia is really an opportunity to learn the limits of the medicalization of life and death and to recover an appreciation of living with and against mortality. It is an opportunity to remember and affirm that there remains a residual human wholeness - however precarious - that can be cared for in the face of incurable and terminal illness. Should we cave in, should we choose to become technical dispensers of death, we will not only be abandoning our loved ones and our duty to care; we will exacerbate the worst tendencies of modern life, embracing technicism and so-called humanness where encouragement and humanity are both required and sorely lacking."³

Over 170 years ago, a medical student at Gottingen by the name of Carl Friedrich Heinrich Marx wrote his doctoral thesis, *De euthanasia medica*, "Medical Euthanasia"⁴, by which he meant not active euthanasia, the killing that many are demanding as an alternative to a wild medicalized death, but rather the passive good death, the peaceful death of skillful palliation that today defines hospice care. Almost two centuries ago this newly minted *Med. et Chir. Dr.* from his ancient univer-



sity in Brunswick reminded his fellow academics of that "great Englishman," who had written 200 years earlier urging physicians "to stay with the patient after he has given up," and "to acquire the skill and to bestow the attention whereby the dying may pass more easily and quietly out of life."

Marx's recommendations were strikingly similar to the principles of hospice today; he would have understood, as perhaps would Bacon, the notion of physician assisted living [PAL] during life's final exit. "Most physicians," he wrote, "once they see the expected result of their treatment to be wanting ... start to lose interest themselves." He even mentions a program at Heidelberg headed by a Prof. Mai, and funded by Amalia, Duchess of Baden, that provided training to women attendants in caring for the sick and the terminally ill. Marx recommended that these caregivers be "considerate, watchful, quiet, clean, free of prejudice toward people ... and adhere to the doctor's orders with greatest obedience." He described the care of bedsores, and that the "doctor will with his own eyes repeatedly search for them"

Marx asked, "What good will it do the incurable patient to apply dangerous and dubious therapeutic measures? The entire plan of treatment will here confine itself within 'symptomatic and palliative medication.'" He even reminded his physician colleagues to see that the patient's dry tongue and pharynx be moistened. He urged "soothing, soporific, sedative, analgesic" medicines, and noted that "... narcotics are of enormous help." But later he added the essential caveat, "... and least of all should he be *permitted* [italics mine], prompted either by other people's requests or by his own sense of mercy, to end the patient's pitiful condition by purposely and deliberately hastening death. How can it be permitted that he who is by law required to preserve life be the originator of, or partner in, its destruction?"

In Marx's brief thesis, written in 1826 upon his being admitted to the faculty at Gottingen, we can find all the principles of hospice care and of

physician care at the end of life embodied in the PAL program. Nothing new here. But even he was not the originator; we find them not only in Bacon, but in the ancients - Pliny, Cicero, Seneca, the Bible. They are embedded somehow in our nature, and even, as Lewis Thomas once suggested, in nature itself: why else the endomorphins? Concerning them he wrote, "If I had to design an ecosystem in which creatures had to live off each other and in which dying was an indispensable part of living, I could think of no better way to manage."

But when endorphins are not enough for the kinds of nonviolent, prolonged deaths that we often produce and must endure, we have the means and the inherent mercy to ease the passage. We should pay more attention to the business of dying. My Harrison's *Principles of Internal Medicine* devotes one and one half pages out of 2,443 to this matter, but it does address the physician's role: "First of all, the patient must be given the opportunity to speak to his physician and to ask questions."

That is what the PAL program as a part of the advanced directive is all

about. It frees patients who are prepared to plan for the inevitable event to consider the options, discuss them with their physicians and families, choose, and then say with Seneca: "I am ready for death, hence I may enjoy life."

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— Robert U. Massey, MD

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A Plague Upon Your Cattle

"Behold, the hand of the Lord will fall with a very severe plague upon your cattle which are in the field." Thus did the Bible [Exodus 9:3] describe the fifth misfortune visited upon Pharaoh's nation. The description is too meager to allow a confident diagnosis but it may have been the communicable disease later described by the Greeks as anthrax [Greek, meaning coal, as in the word anthracite.]

There was periodic mention of a mortal disease of cattle throughout the Middle Ages but not until the 17th century did the disease reach epizootic proportions. In England it was referred to as the black bane [from an Old Germanic word, *bann*, meaning murderer.] The disease was later referred to as woolsorters' disease since it was most frequently encountered in those whose labors involved intimate contact with animal hides or animal hair including wool. Anthrax was primarily a disease of domesticated animals, although it secondarily affected humans on occasion.

The infectious nature of anthrax was confirmed in the early years of the 19th century. In 1876 Robert Koch announced the isolation of a rod-shaped bacterium, *Bacillus anthracis*, as the causative agent and five years later Louis Pasteur produced an effective vaccine against anthrax thus diminishing a terrible threat to the French livestock industry.

The anthrax bacillus is a bimodal organism: When proliferating in the animal [or human] body it actively elaborates its deadly toxins; but when exposed to air it reverts to a rounded spore-like state quite resistant to the bacteriocidal effects of drying. It can remain in soil, hibernating for decades before its reactivation after entering the body of some grass-eating animal. The spore is then transformed into the active, bacillary form causing fever, hurried respiration, extensive bleeding from all orifices, convulsions and death within days.

The character of the human disease depends upon the pathway by which the anthrax organism enters the victim's body. In the great majority of cases, perhaps 95%, the anthrax spore enters through some minor skin abrasion establishing itself first as a localized cutaneous infection, [malignant pustule is yet another name of the disease.] The sore rapidly turns black [hence the name anthrax.] This is a relatively mild form of anthrax with a low mortality rate. If, however, the spores are breathed into the victim's lungs, an acute, febrile disease ensues with an extremely high mortality rate. When the organism is ingested it may then produce

diffuse hemorrhages of the intestines, pathophysiologically similar to the fatal disease in ruminating animals. This form of human anthrax is rare.

The disease had been well-contained by the 20th century. In nations that could afford it, herds of cattle, goats and sheep were routinely vaccinated against anthrax. Workers in industries dealing

with potentially infected hides from overseas sources were protected by mass sterilization of imported animal skins. [Hot formaldehyde fumes kill the anthrax spores adherent to the hides.]

The number of human cases of anthrax has progressively diminished. At the turn of this century, about 200 cases were encountered in the United States each year. By 1950, this had diminished to about 30 cases annually. By 1970, the yearly number had dropped further to about five. And in the last 10 years, there have been only four nonfatal cases reported in the United States.

Thus, by 1980, anthrax had become an infectious disease more of historic than epidemiologic interest. Rare cases did crop up, contracted from such bizarre sources as shaving brushes manufactured overseas and made of anthrax-contaminated pig-bristles; or bongo drums using unsterilized rawhide. While anthrax remained a palpable problem in the less-developed nations, the US Public Health Service had confidently dropped anthrax from its active list of perilous diseases.

Human resolve had thus achieved another success in protecting humans from the ravages of infectious agents; but human iniquity was ever capable of reversing such hard-fought gains. By 1975, despite a treaty banning biological warfare, there were hints that the Soviet Union had modified anthrax spores to be used as a airborne weapon of mass destruction.

In 1980 the Soviet press carried vague stories of an anthrax epidemic involving Sverdlovsk, a Russian city about 1,400 kilometers east of Moscow. Independent observers from the West were later allowed to investigate. They determined that there were 96 verified cases of human anthrax with 64 deaths [67% case fatality rate]. Four irrefutable features make this outbreak uniquely distinguishable: First, the fatal cases were all pulmonic suggesting an airborne source of the incriminating spores; second, virtually all of the human cases had lived or worked in a narrow but elongated band of territory extending to the southeast of the city [this zone, incidentally, paralleled the prevailing wind on the presumed day when humans and cattle became infected]; third, many cattle in this same zone of infectivity were simultaneously infected with anthrax; and fourth, the Soviet military establishment maintained a military microbiology facility at the apex of this zone of infectivity. The investigating team stated: "We conclude that the outbreak resulted from the windborne spread of an aerosol of anthrax pathogen, that the source was at the military facility and that the escape of pathogen occurred during the day on Monday, 2 April. The epidemic is the largest outbreak of human inhalation anthrax." In May, 1992, Boris Yeltsin was quoted as saying: "The KGB admitted that our military developments were the cause."

Art imitates nature; and cold reality sometimes contrives to mirror science-fiction. A disease thought to have retreated into the recesses of history may arise again, inadvertently or purposefully, from sites such as Sverdlovsk, Baghdad or even the streets of middle America. Said Exodus: "Yet will I bring one plague more upon the people."

— Stanley M. Aronson, MD



Ischemic Stroke Syndromes:

Classification, Pathophysiology and Clinical Features

William M. Stone, MD

About one quarter of strokes are caused by hemorrhage; the rest are due to ischemia. This discussion will focus on strokes which occur when inadequate tissue perfusion is present long enough to produce brain cell death or ischemic infarction. When there is no leakage of blood from vascular structures within or bordering such an area of tissue damage, the lesion is described as a bland infarction. When there is reperfusion of a necrotic region and subsequent diapedesis of red cells through damaged capillary or arteriolar walls, the lesion becomes a hemorrhagic infarct.

Further subdivision of ischemic stroke is based upon whether the underlying mechanism of circulatory interruption is due to thrombosis or embolism. Both processes may occur in a variety of pathologic settings, including coagulopathy, inflammation, congenital vascular atresia, fibromuscular hyperplasia, dissection, kinking, and trauma; but the most common context in which thrombosis and embolism arise in atherosclerosis is arteriosclerosis. Sometimes the process by which a large blood vessel becomes narrowed or occluded by thrombus adherent to an underlying atheromatous mural plaque is termed atherothrombosis. In cases in which thrombus becomes dislodged from its arterial plaque attachment and moves on to occlude a more distal vessel, the process of artery-to-artery thromboembolism is invoked. In still other cases the source of blood-borne thrombotic material may be the heart: in this instance the term cardioembolism is applied. Thrombosis or embolism may occur on a microscopic basis within the 100-400 micron in diameter penetrating arterial branches of the anterior, middle, and posterior cerebral arteries and the communicating and basilar

arteries. When it does, it produces a roughly spherical infarction, usually 2-20 mm in diameter called a lacune. Often such small vessel strokes are seen in the context of sustained hypertension which sets the stage for micro-thrombosis or embolism by inducing fibrin deposition in the arteriolar wall leading to fibrinoid necrosis or lipohyalinosis.¹

The above discussion of basic stroke pathophysiology can be related to clinical neurological phenomenology.

SYNDROMES OF LARGE VESSEL THROMBOSIS AND EMBOLISM: Carotid Artery

Transient ischemia and frank infarction secondary to atherothrombosis of the carotid artery and its branches comprise a major part of stroke morbidity. The location of the atheroma is usually within a few millimeters of the bifurcation of the common carotid. Plaque, ulcerations and adherent thrombus may be found in the carotid sinus as well as within the proximal portions of the internal and external carotid arteries. Stenosing lesions of this type comprise the vast majority of carotid lesions, but on occasion such occlusive disease is found in the intracavernous portion of the artery and even more rarely within the petrous or intracranial portion of the internal carotid artery.

It is now generally agreed that most strokes and TIAs arising from carotid artery atherothrombosis occur as the result of artery-to-artery embolism composed of thrombus, fibrin, or platelet aggregates or from embolism

Abbreviations Used:

ACA	anterior cerebral artery
AICA	anterior inferior cerebellar artery
BA	basilar artery
MCA	middle cerebral artery
PCA	posterior cerebral arteries
PICA	posterior inferior cerebellar artery
SCA	superior cerebellar artery
THA	transient hemipheric attacks
TIA	transient ischemic attack
TMB	transient monocular blindness
VA	vertebral artery
VB	vertebrobasilar [artery]

from a cardiac source.² The minority of ischemic events are related to hemodynamic events. It is also well known that the carotid artery may gradually develop complete occlusion with no clinical symptoms, and it must always be remembered that the pace of onset of obstruction and the efficacy of collateral circulation are critical determinants of the neurological deficit. In general, when the occluding process develops slowly, the collateral vasculature may prevent or minimize ischemic damage. If the occlusive event is precipitous, as is the case with large emboli or dissection, then the volume of infarcted brain may be larger and clinical deficits more severe.

Transient Ischemic Attacks

Carotid territory strokes may be heralded by temporary, focal neurological deficits of ischemic etiology generally lasting less than 24 hours: a transient ischemic attack (TIA).

At least half of carotid artery stroke patients have one or more TIAs before permanent infarction occurs. TIA may not always lead to infarction; indeed, up to a third of patients with carotid TIAs do not ultimately go on to infarction or recurrent TIA. Nonetheless about one-third of patients with

TIA's ultimately go on to have infarction, though not always within the ipsilateral carotid territory. Overall, the relationship between antecedent TIA and carotid territory stroke is much stronger than with strokes in other vascular territories since there is only about a 10% incidence of TIA with all stroke types taken as a whole.³

Transient monocular blindness (TMB) also known as amaurosis fugax is an important carotid TIA syndrome and is characterized by patients describing their monocular visual alterations as "blurred", "cloudy", "blackening" or "greying-out." The classically taught "shade" or descending "curtain-like" obscuration is present in the minority of cases. The duration of these symptoms is usually less than 5 minutes and rarely exceeds 30 minutes. TMB is only very rarely present concurrent with neurological deficit referable to the brain and eye or head pain are not usual accompaniments.⁴ Ophthalmoscopy performed during TMB attacks almost invariably does not disclose any intravascular material. The yellow, birefringent cholesterol crystalline plaques sometimes seen within the retinal arteries of patients with systemic arteriosclerosis (known as Hollenhorst plaques) are not thought to cause TMB, and, if present, are incidental to the visual symptoms. They may, however, be a marker for the presence of carotid-bifurcation atherothrombotic disease.⁵

Transient hemispheric attacks (THA) are characterized by symptoms reflecting temporary ischemia within a part of the cerebrum supplied by the anterior, middle or anterior choroidal arteries severe enough to produce dysfunction. THAs are another important carotid TIA syndrome. Disordered motor and/or sensory function of the contralateral limbs are most commonly reported. Problems with speech articulation due to facial or labial weakness may occur. When the dominant hemisphere is involved, disordered language function (dysphasia or aphasia) may be present. THAs generally last less than 10 minutes. When they last hours at a time, the suggested

mechanism may be intracranial branch occlusion by an embolic source more proximal than the carotid, such as the ascending aorta or the heart. It is quite rare for patients to experience THA and TMB simultaneously; but when they occur sequentially or in an alternating manner, it may indicate severe extracranial atherothrombotic carotid disease.⁴

When carotid and collateral occlusive disease is severe enough to compromise flow to the distal-most fields of the major arteries, a borderzone infarction results. When fully manifest, the damage extends as a band from the frontal pole posteriorly to the occipitoparietal region, sparing the parasagittal, lateral (perisylvian) and primary occipital aspects of the hemisphere. The resulting clinical syndrome can be distinctive and includes weakness and sensory disturbance of the contralateral shoulder usually with a notable absence of severely disturbed language, vision or lower limb function.⁶

Hemispheric infarction may occur in carotid occlusive scenarios by other mechanisms. Anterograde propagation of a thrombus up the internal carotid artery to the circle of Willis and even into the proximal anterior ACA or MCA can occur. The clinical deficits are often catastrophic, producing major motor and sensory deficits of the contralateral limbs and also severe language and cognitive dysfunction, especially when the dominant hemisphere is involved.⁷ Distal embolization of thrombotic material arising from extracranial carotid atherothrombosis is much more common than anterograde thrombus propagation. The stroke symptoms from such artery-to-artery embolic events are heterogeneous and clinically indistinguishable from aorto- or cardioembolic infarctions. The deficits depend in large part on the caliber, location and duration of occlusion of the intracranial vessel involved by the embolus. Thromboemboli often are not structurally stable. Natural fibrinolytic activity often causes the lysis of the occlusive material into pieces small enough to move further out in

the arterial tree. Angiographic studies done after a delay of more than 48 hours often fail to document any embolic material even in patients with clear and persistent neurological deficits ascribable to embolic infarction.⁸ Thus the signs and symptoms noted at presentation often change over the hours following onset. There are some recognizable syndromes, however, when emboli lodge in the stems of MCA and ACA.

Middle Cerebral Artery

When the MCA is occluded at its stem, the deep penetrating lenticulostriate arteries which supply parts of the internal capsule and basal ganglia may be blocked and there is compromised flow to the more superficial branches supplying the overlying cortex. An infarction within these territories produces contralateral hemiplegia, hemianesthesia and homonymous hemianopia. When in the dominant hemisphere, severe aphasia is present; and when in the non-dominant hemisphere, hemineglect or other agnostic deficits are often present.

Anterior Cerebral Artery

Occlusion of the stem of the ACA distal to the anterior communicating artery (and thus beyond a point that would allow for potential collateral blood supply from the contralateral carotid) causes sensorimotor dysfunction of the contralateral foot and leg, with relative sparing of the arm and face but with variable behavioral disturbance. In some individuals both ACAs arise from a single stem; if this stem is occluded the resulting bilateral infarction produces marked spastic paraplegia and behavioral syndromes, including urinary incontinence, apathy, distractibility, slowness of thought, paucity of insight and movement and sometimes mutism.

Middle Cerebral Branches

If an embolus occludes one of the first order divisions of the middle cerebral artery, deficits arise that may be difficult to distinguish from internal carotid occlusive syndromes. Superior

division of the MCA territory infarction yields contralateral, dense sensory and motor appendicular and facial weakness and, if within the dominant hemisphere, severe aphasia. Inferior division infarctions may be characterized by auditory language and repetition deficits and hemianopic visual problems. When second order divisions of the MCA are occluded (usually by emboli), the stroke symptoms are less global. If the first branch of the superior division of the MCA (the ascending frontal artery) is occluded, then the third frontal convolution is infarcted, and there is contralateral brachiofacial weakness. When this occurs in the dominant hemisphere, the damaged region includes Broca's area; and the initial presentation also includes mutism or dysfluency with little or no difficulty in verbal comprehension. When the territory of the second branch of the superior division of the MCA (the rolandic branch) is infarcted, there is contralateral sensory and/or motor weakness accompanied by articulatory difficulties (dysarthria), but not aphasia. Occlusion of the third (ascending parietal) or fourth (posterior parietal) branches of the superior division of the MCA produces syndromes characterized by disconnected language function such as conduction aphasia and impairment of planned motor tasks (ideomotor apraxia). Often there is no concurrent primary sen-

sory or motor dysfunction on either side of the body. The specific syndromes associated with occlusion of the branches of the inferior division of the MCA of the dominant hemisphere include Wernicke's aphasia, often in combination with contralateral superior quadrantanopia because of infarction of white matter tracts deep to the posterior sylvian region including the optic radiation.⁹ (Figure 1)

Anterior Choroidal Artery

Though sometimes clinically unrecognized because of the mild nature of the associated deficit, infarctions within the anterior choroidal artery can result in contralateral hemiplegia and hemihypesthesia along with hemianopia. The territory of damage includes the posterior limb of the internal capsule, other nearby white matter tracts, and the lateral aspect of the lateral geniculate body.¹⁰

Vertebrobasilar System

Large vessel infarction within the territory of vertebrobasilar (VB) and posterior cerebral arteries (PCA) produce a heterogeneous array of stroke syndromes. As with the carotid artery and its cephalad divisions, atherothrombosis, artery-to-artery embolism, cardioembolism and hemodynamics are generally involved. Variations of anastomatic anatomy, coagulation and duration of occlusion

remain important mitigating factors. The clinical characteristics of the stroke syndromes of the VB and PCA are often distinct from those of the carotid, middle, anterior and anterior choroidal arteries. This relates in part to their frequent manifestations with ipsilateral eye movements and cerebellar dysfunction. The unique nature of these strokes is due to the compactness of brainstem structure, the presence of nuclei as well as tracts and the nature of the vascular anatomy.

Arising as the first branch of the subclavian arteries, the VAs enter the foramen transversaria of the fifth or sixth vertebra and ascend through more rostral transverse foramina to exit at the second cervical vertebral level and loop posterolaterally, circling the posterior arch of the first cervical vertebra, and enter the cranium between the atlas and the occiput, piercing the dura as the foramen magnum is traversed. At the level of the pontomedullary junction there is a confluence of the VAs to form the BA which courses cephalad to the pontomesencephalic junction, where a tetrafurcation gives rise to the paired superior cerebellar and posterior cerebral arteries. At the crux of the basilar tetrafurcation arise small caliber vessels which penetrate the thalamus, hypothalamus and rostral midbrain. Perforating branches of the PCA (the thalamoperforants) also supply diencephalic structures. An orderly series of VA and BA branches derive from their parent vessels. Whether they are deep, small caliber, midline penetrators or circumferential branches of medium caliber, their branching angle tends to be acute, at times approaching perpendicular. The larger, named branches such as the posterior inferior cerebellars (PICA) which arise from the VAs at the level of the cervicomedullary junction or the anterior inferior cerebellar arteries (AICA) which arise from the BA at the lower to mid pontine level are usually but not invariably paired. (Figure 2) Though some collateralization occurs among these VA and BA branches their anastomatic capacity is much more limited than is the case for vessels anastomosing with the circle of Willis. In

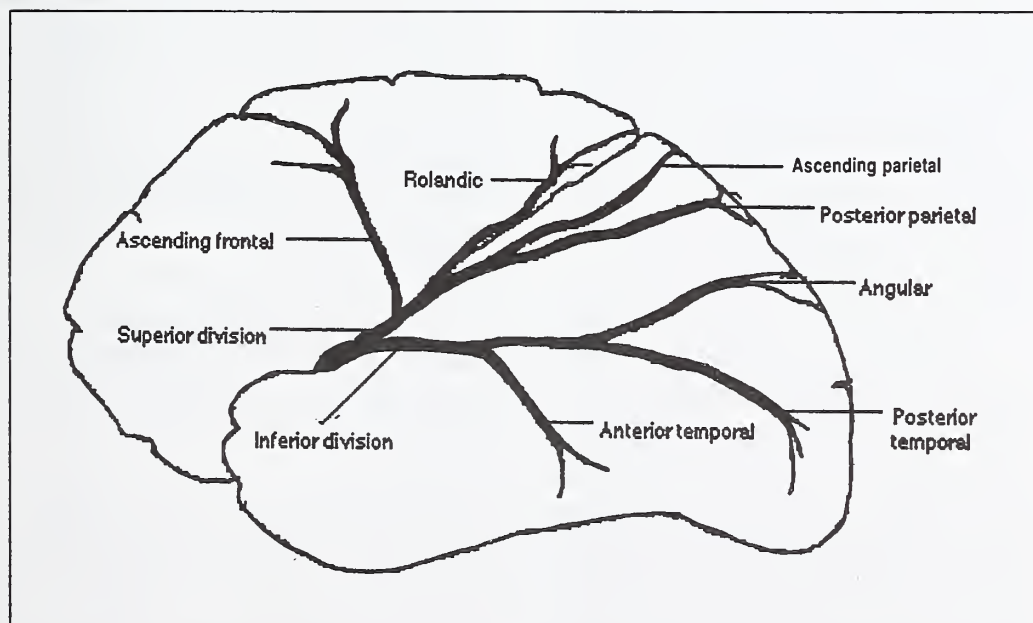


Figure 1.

Diagram of the lateral aspect of the left cerebral hemisphere showing the major branches of the middle cerebral artery in relation to the cortical surface

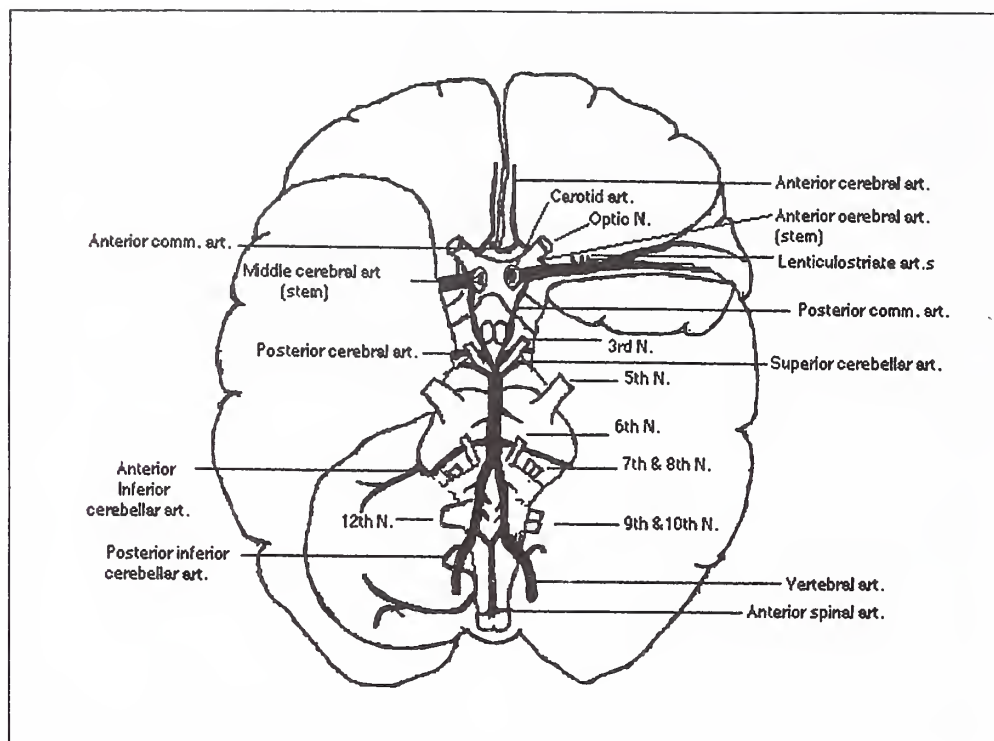


Figure 2.

Diagram of the base of the brain showing the circle of Willis and the major vessels of the vertebrobasilar system in relation to cerebral, cerebellar, brainstem and cranial nerve structures.

the case of the small caliber paramedian and short lateral circumferential arteries there is essentially no opportunity for collaterals; they are end arteries. Some variability in anastomoses, especially at the rostral end of the VB and PCA system is attributable to embryological factors. During early fetal development the hindbrain is irrigated by vasculature including the precursors of the PCAs which derives its major connections from the carotid circulation. Later in fetal development these connections regress leading to a more clear cut relationship of the PCAs with the VB circulation. At birth this remodeling is not always complete and there may be persistence of the fetal pattern. Thus in up to 25% percent of adults or children one PCA derives from the internal carotid (and has no anastomosis with the basilar) and the other PCA arises from the BA and anastomoses with the ICA via a posterior communicating artery. In a small percentage of cases both PCAs derive solely from the internal carotids.¹¹

The subclavian steal syndrome occurs when a stenosis is present in the subclavian artery proximal to the origin of the vertebral artery. A demand for blood flow to the arm is met by a siphoning effect on the blood within the ipsilateral VA causing it to flow in

a retrograde fashion. This in turn draws blood from the contralateral VA and directs it away from the BA resulting in diminished perfusion of the hindbrain. Symptoms are variable but often include dizziness, lightheadedness and moderate posterior headache. Ataxia, paraparesis, diplopia, drop attacks without loss of consciousness and syncope may occur. Sometimes the onset or severity of symptoms depends on the position or muscular activity of the arm ipsilateral to the subclavian stenosis.¹² Actual infarction of the rostral spinal cord, brainstem, cerebellum or occipital lobes is relatively uncommon. Individuals with persistence of the fetal pattern of posterior cerebral artery circulation in whom the upper portion of the BA cannot derive blood via caudally directed flow may be particularly symptomatic from subclavian steal.

The relatively prolonged course of the vertebral arteries through the transverse foramina render them susceptible to mechanical compromise by kinking during head turning and from impinging vertebral spondylotic osteophytes. TIA and infarction are both reported complications but are rare. Angiographically documented asymptomatic cases of vertebral obstruction during head turning are well known.

Intimal injury and thrombosis of the vertebral artery may result in transient ischemia or infarction. The most common site of occlusion is at the second cervical level. It is postulated that the translation of torsional and shearing force to the vessel is greatest at this point where it is relatively fixed upon exiting the transverse foramen.¹³

Though serving the potentially protective role of a dual source of blood for the BA, the VAs also may have the more detrimental effect of acting as a dual conduit for embolic material. Once emboli enter the BA they often will lodge at the "saddle" of the tetrafurcation, laminar flow having directed them past the origins of the acutely branching vessels. Thromboembolic occlusions of this type may produce a distinct array of symptoms encompassing the top of the basilar syndrome.¹⁴ Because infarctions within this territory involve portions of the midbrain, thalamus, occipital and temporal lobes (often bilaterally), symptoms include abnormalities of pupillary size, shape and reactivity along with deficits of aberration of oculomotor function, especially vertical gaze and convergence.

Damage to the paramedian regions of the midbrain and thalamus which comprise parts of the reticular activating system results in abnormalities of alerting, arousal and sleep.¹⁵ Behavioral disturbances including confabulation with or without memory disturbance may be present and sometimes noted is a peculiar form of positive visual phenomenon termed peduncular hallucinosis. These hallucinations occur at night or at sundown and are generally perceived in vivid colors containing formed visual elements that may not completely fill the visual field.

Transient or persistent movement disorders including hemiballism or hemichorea may accompany infarcts of the subthalamic or thalamus. Infarction within the territory of perforating vessel from the proximal PCA into the cerebral peduncle may cause contralateral hemiplegia and ipsilateral third nerve dysfunction. When the occlusion at the basilar apex is large enough to occlude one or both PCA or when fragments of the embolus ad-

vance up into the PCA there are prominent visual field abnormalities including hemianopia or cortical blindness.

Posterior Cerebral Artery

Emboli that ascend the basilar without lodging at the basilar apex will generally come to rest in one or both PCAs. The carotid circulation may conduct emboli to the PCA in individuals with persistence of fetal connections or when hemodynamic factors favor caudal flow through posterior communicating arteries. The source of emboli most often is a more proximal artery, but cardioembolism is also common. Atherothrombosis of the PCA is relatively uncommon, but when it occurs is generally in the proximal segment of the vessel. Sometimes thrombus may spread by contiguous ascent from the basilar apex.

PCA infarction rarely involves the entire arterial territory; and the variability of the resulting clinical deficits of primary sensory, visual and behavioral function depend upon the degree of damage to the thalamus, occipital and inferomedial temporal lobes respectively. Blockage of vessels derived from the proximal PCA can cause infarction in sensory and motor nuclei of the thalamus and nearby subthalamic structures. Such is the case when the thalamogeniculate branch is occluded, producing a distinctive syndrome of transient contralateral hemiballismus and hemiparesis with persistent hemihypesthesia and fleeting but recurrent contralateral pain described first by Dejerine and Roussy in 1906.¹⁶ When PCA infarction occurs as the result of occlusion beyond its proximal stem, obtundation and sleep disturbances are not present as reticular activating structures are spared. Hemiparesis and third nerve dysfunction are absent because the cerebral peduncle is not injured. Unilateral infarction of cerebrocortical structures within the occipital cortex manifest as contralateral hemianopia often sparing the macular region due to the dual supply of the occipital pole by PCA and MCA or ACA branches. With incomplete lesions of the primary visual receptive area of the calcarine region of the occipital lobe, the hemianopic loss

may be more marked in the contralateral superior fields and less impaired in the inferior fields. With large cortical lesions involving occipital and temporal regions, a variety of behavioral syndromes may be present. Lesions of this type in the dominant hemisphere can produce alexia, anomia and amnesia. These deficits often occur without agraphia. The ability to name colors or recognize nonverbal symbols such as musical notes may be particularly impaired. When the non-dominant hemisphere is involved, spatial disorientation and the anomia for familiar faces (prosopagnosia) can occur. Bilateral PCA infarcts of the temporal lobes may produce lesions of both hippocampi leading to a permanent severe amnesia termed Korsakoff's state. Bilateral infarction of the occipital lobes can produce Balint's syndrome of disordered volitional eye movements (ocular apraxia), imprecise visually guided eye movements (ocular ataxia), impaired visually guided limb movements (optic ataxia) and the inability to recognize and name multiple concomitantly viewed objects (simultanagnosia).¹⁷

Transient ischemia and frank infarction secondary to atherothrombosis of the carotid artery and its branches comprise a major part of stroke morbidity.



Basilar Branches

Occlusion of the large circumferential branches of the vertebral or basilar arteries produce recognizable syndromic strokes. The usual pathogenesis is atheroma or clot material within the parent artery which blocks flow through the orifice of the branching vessel. The acuity of the branching angle offers protection from embolic events though rare emboli

within the circumferential arteries are found at autopsy. Atheromatous occlusion of these vessels is also rarely found.

The PICA supplies blood to the lateral portion of the medulla, which includes the inferior cerebellar peduncle, vestibular nuclei, descending sympathetic and trigeminal tracts, spinothalamic tracts and the nucleus ambiguus and solitary tract and nucleus. Lateral medullary infarction produces Wallenberg's syndrome of ipsilateral limb and gait ataxia, dizziness, nystagmus, loss of pain and temperature sensation on the face with loss of corneal reflex, Horner's syndrome, hoarseness and palatal weakness with loss of taste and contralateral loss of pain and temperature sensation on the body.

The AICA territory includes the middle cerebellar peduncle, fifth nerve sensory nucleus and tract, seventh nerve and nucleus, eighth nerve, vestibular nuclei and the descending sympathetic tracts. AICA-related lateral pontine infarction produces a syndrome similar to Wallenberg's; but instead of hoarseness, palatal weakness and loss of taste, there is ipsilateral facial paralysis and deafness.

The SCA supplies the superior cerebellar peduncle, dentate cerebellar nucleus, lateral and medial lemnisci and the descending sympathetic tracts. Superior cerebellar artery territory infarction causes ipsilateral limb and gait ataxia, Horner's syndrome and tremor while contralateral findings may include limb dysmetria, loss of pain and temperature sensation over the body and face, loss of limb position sense and decreased hearing. Obtundation is not an integral part of these syndromes since the circumferential branches do not irrigate the midline brainstem in which the ascending reticular activating system resides.

Infarctions within the territory of the short circumferential or midline branches of the VA and BA also manifest with distinct stroke syndromes. Such is the case when perforating branches from the stem of the anterior spinal artery become blocked by atheroma or clot. If collateral flow



from the contralateral anterior spinal is inadequate, infarction of the medial caudal medulla produces contralateral limb but not facial paralysis, contralateral loss of position and vibration and ipsilateral weakness and later atrophy of the tongue: the medial medullary syndrome. Paramedian BA penetrating branch occlusions generally due to ostial encroachment by atheroma or basilar thrombus produce dysfunction of corticospinal tracts and crossing pontocerebellar tracts in the pontine base and produce variable signs of paralysis and ataxia which is often bilateral and associated with extensor plantar responses. In the "locked-in" syndrome, patients with such tegmental-basal pontine strokes are unable to move anything but their eyes despite the preservation of normal consciousness. When the ischemic insult extends into the pontine, tegmental midline nuclei such as those of the fourth and sixth nerves results include dysconjugate eye movements. Other midline structures such as the parapontine reticular formation and the medial longitudinal fasciculus which integrate lateral eye movements may be involved with resulting paralysis or aberration of lateral gaze, including para-abducens palsy and internuclear ophthalmoplegia respectively.¹³

Basilar Artery

There is no homogeneity to the syndromes or prognosis of patients with complete occlusion or severe

stenosis of the BA itself. When the occlusive process is gradual and collateral flow is present, the deficits may be focal and survivable. But when onset is sudden and collateral is limited, the syndrome is devastating and usually fatal. Such patients experience a short prodrome of headache, confusion and dizziness, followed by a rapid progression through stupor to coma. Dysarthria and lateralized paresthesiae are common, as are pupillary and ocular movement abnormalities. Facial palsy and hemiplegia or quadriplegia accompanied by bilateral extensor plantar reflexes are generally seen. Crossed cranial nerve and hemiplegia are often manifested during the progression of signs. Though fluctuations in depth of coma and severity of paralysis often occurs early, death most frequently occurs within days to weeks.¹⁸

SYNDROMES OF SMALL VESSEL THROMBOSIS AND EMBOLISM

Lacunar strokes, which comprise the most common paradigm of small vessel infarction, account for 10% of all strokes. Several distinct lacunar syndromes are recognized: the most common is pure motor hemiparesis. The clinical characteristics of this syndrome include severe hemiparesis or hemiplegia involving the limbs, face and trunk often with associated dysarthria. Notably absent are sensory disturbance, visual or language deficits. The site of such infarctions are within the corona radiata, internal capsule, cerebral peduncle, pons and rarely the medullary pyramid. The pure sensory stroke produces hemisensory deficits involving the face, limbs and trunk contralateral to the small infarction in the ventral posterior thalamic nucleus which causes the syndrome. Lacunar infarction in the genu or anterior limb of the internal capsule or pontine base produce clumsy hand-dysarthria syndrome which manifests clinically as clumsiness of the contralateral hand and tongue with contralateral facial paresis. Homolateral ataxia and crural paresis result from pontine lacunes involving post-decussating cerebellar tracts and pre-decussating corticospinal tracts. The resultant signs are of mild con-

tralateral hemiparesis involving leg more than arm or face with more marked ataxia of the weak limbs. Bilateral lacunes within the internal capsule in perithalamic locations may result in a mutism syndrome. The accrual of multiple lacunae within the internal capsules of both hemispheres may result in a pseudobulbar syndrome in which there is dysarthria, hyperactive gag reflex with dysphagia, spasticity especially of the lower limbs extensor plantar reflexes, gait apraxia with small hesitant steps and emotional incontinence.¹⁹ This lacunar state is a major part of subcortical atherosclerotic encephalopathy. There is evolving evidence that microvascular occlusive disease can be due not only to thrombotic or obliterative disease but also to embolic processes. Intra and extracranial arterial sources are implicated as is cardioembolism of micro-particulate matter.

NON-ATHEROSCLEROTIC SYNDROMES

There are numerous non atherosclerotic causes of stroke including homocysteinuria, Fabry's disease, Marfan's syndrome, Sneddon's syndrome, moya moya disease and others. Most are either rare or do not produce typical clinical syndromes. One non-atherosclerotic process that does produce a recognizable symptom complex is carotid artery dissection, which often presents with sudden onset of contralateral hemiplegia or hemisensory deficits, with ipsilateral Horner's syndrome often with ipsilateral frontal or periorbital headache. Another important group of non-atherosclerotic thrombotic strokes are associated with cerebral venous occlusion and secondary brain infarction. Though infrequent in comparison to arterial strokes, these venous infarcts are not unusual in at-risk patients, such as those who are postpartum or have malignancy or craniofacial infections, especially otitis media. Symptoms of increased intracranial pressure, such as headache, vomiting, convulsions and obtundation, are frequent. Focal motor, sensory or behavioral deficits are common when the superior sagittal si-

nus is occluded. Disordered eye movements and upper and mid-facial numbness are common features of cavernous sinus thrombosis, along with proptosis and retro-orbital pain. Secondary hemorrhagic transformation is a common delayed consequence of venous infarction.²⁰

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The Role of Correctional Facilities in Public Health:

The Example of Sexually Transmitted Diseases

Anne C. Spaulding, MD

The October 1997 *Medicine & Health/Rhode Island* focused on sexually transmitted disease (STD) in our state. Sex industry workers and injection drug users were among the groups highlighted as high risk and in need of focused STD prevention efforts.¹ The Department of Corrections is a logical place for Rhode Island to concentrate its endeavors. Indeed, linking STD prevention and treatment to the correctional health care program may be the most efficient way to improve the health status of the state as a whole.

Because of the nature of the inmates' offenses, correctional facilities house people most vulnerable for developing STDs. Prostitutes and their partners are at high risk for acquiring chlamydia, syphilis, or one of a multitude of other sexually transmitted diseases, including HIV. Fifty percent of female inmates are incarcerated for solicitation. Also, our state punishes the possession of drugs with prison terms. Currently 19.4 % of Rhode Island prisoners are serving sentences for drug-related offenses, and substance abuse may have contributed to other offenses (e.g., robbery, to finance a drug habit).

Beyond the obvious risk for STDs that the criminal behavior poses, inmates are vulnerable in other ways. Poverty and mental illness are more prevalent in the prison population than in society as a whole. Years ago those at the margins of society may have lived in a poor house or a psychiatric hospital; today this same population ends up in jail. The setting of the Rhode Island correctional facilities is a very visible illustration of the role of a modern jail and prison. Rhode Island Department of Corrections, the state's combined jail and prison system, is situated on a tract of land in Cranston, RI, known as the Howard Complex.

Since the prison moved from downtown Providence in the 19th century, the tract has been home to a correctional facility, poor house and a psychiatric hospital.²

With time, the apportionment of beds has changed. Currently, the inmate population is at a record high of 3400, despite a state population (about a million) which has experienced no recent growth. Fifteen thousand admissions occur yearly, slightly less than 1.5% of the population, since some individuals are committed more than once in a given year. When the state's population was 950,000 in 1970, the mental hospital had about 1200 to 1300 beds. Deinstitutionalization of the mentally ill, starting in the early 1970's, shrank the number of beds to about 100 for the mentally ill at the state hospital on the Howard Complex. A "poor house" which once rivaled the state prison in size has closed. The Welcome Arnold Shelter on the Howard Complex grounds serves about 100 homeless people a night. The poor and mentally disturbed make up a higher portion of the incarcerated population than represented in the general population. Over 25% of women incarcerated in RI are on some psychotropic medication. Poverty and mental illness can lead to less access to routine medical care, lower educational achievement, more victimization, and, consequently, greater vulnerability to sexually acquired diseases.

STDs: THE SCOPE OF THE PROBLEM

The rate of STDs is higher in the inmate population than the general population. At intake, RI inmates are routinely tested for syphilis and HIV.

Abbreviations Used:

GC	gonococcus
HIV	human immunodeficiency virus
LCR	ligase chain reaction
RIDOC	Rhode Island Department of Corrections
STD	sexually transmitted disease

Approximately 15% of all cases of syphilis in the state are detected each year at RIDOC, despite testing fewer than 1.5% of the state's population yearly (Frank Tedino, RI Department of Health, personal communication). At the beginning of the AIDS epidemic, 40% of the HIV diagnoses in the state were made upon jail entry.³ With the maturation of the epidemic, this percentage is now about 35%.

While incoming inmates in RI are not screened for gonorrhea and chlamydia routinely, women are tested when a physician performs a pelvic exam, which by policy occurs after confinement for greater than two weeks. Within one week, about half of detainees are discharged. The 10 cases each of gonorrhea and chlamydia detected out of 226 patients tested for suppurative STD in calendar year 1997 probably represent a vast underestimation of the disease prevalence. In the nearby Hampden County, MA Correctional system, 5% of the male inmates were diagnosed with chlamydia.⁴

Several correctional facilities around the country are examining better ways to detect the true prevalence of STDs more accurately. Rapid identification of asymptomatic juveniles with gonorrhea and chlamydia has been achieved in the Los Angeles juvenile detention halls by use of the ligase chain reaction (LCR) urine based technology: 17% of girls and 9.5% of boys were positive for chlamydia; over

90% of the patients were asymptomatic. For gonorrhea, 4% of the girls were positive and 81% of these infections were asymptomatic; 0.7% of the boys were positive and 88% asymptomatic.⁵

THE IMPORTANCE TO INDIVIDUALS AND THE IMPORTANCE TO THE COMMUNITY

The state has an ethical obligation both to those it punishes by confinement and to the society where the offender will eventually return. According to the U.S. Supreme Court case *Estelle vs. Gamble* (1976), deliberate indifference to medical needs constitutes cruel and unusual punishment, forbidden by the eighth amendment to the U.S. Constitution. Along with the military, veterans and Native Americans, prisoners are one of the few groups in the United States who are provided health care.

Some infections have simple cures. For others, treatment can ameliorate the disease course and lessen transmission. Syphilis, even if of indeterminate duration, is probably no longer infectious after treatment with one dose of penicillin. Because of high turnover and often extremely brief stays within the prison system, the newer one-dose regimens for gonorrhea and chlamydia may be more practical than the week-long regimens used in the past. With appropriate discharge planning, treatment for HIV, including protease inhibitors, initiated while a patient is incarcerated, can be continued uninterrupted after release.^{6,7} Lowering HIV viral load with highly active antiretroviral therapy may make a patient less infectious to others.

In the absence of an HIV vaccine, treatment for ulcerative and suppurative sexually transmitted diseases may be the most efficacious means of preventing acquisition of HIV. The term "epidemiological synergy," coined by Wasserheit, describes how both genital ulcerative disease and gonorrheal and chlamydial infections can increase both the susceptibility and transmission of HIV. STDs in either the HIV positive or negative individual member of a sero-discordant couple can in-

The Incarcerated Population of R.I.			
	Male	Female	Total
Population as of 12/31/97	3,038	196	3,234
Total Commitments, 1997	13,682	1,990	15,672
Detainees with Length of Stay \leq 7 Days (9/1997)	51.7%	56.6%	52.4%
Sentences for Drug Related Offences: as of 12/31/97	20.4%	17.5%	20.2%
HIV Seropositivity	3%	6%	3%

crease the rate of HIV transmission 3-5 fold. Furthermore, HIV may prolong the infectious period of ulcerative diseases several fold.⁸

The state has an ethical obligation both to those it punishes by confinement and to the society where the offender will eventually return.



Those treated in prisons may be at higher than average risk for transmitting both the "old" STD's (syphilis, GC, chlamydia, etc.) and HIV. A central concept in the current STD literature is that of the core group. The concept, introduced by Cooke and Yorke in the 1970's in modeling gonorrhea,⁹ has taken on various shades of meaning but essentially the term denotes that a small number of people experiencing a STD are, because of their behavior, more frequently infected and often more likely to

transmit their infection.¹⁰ An infrequent, usually monogamous, client of a prostitute will prove little risk to society as a whole. A crack-addicted woman exchanging sexual services for drugs will augment transmission rates of a disease acquired through her trade. A few promiscuous individuals "amplify" the disease and are "bridges" to previously uninfected groups.

The "reproduction" of an STD can be characterized mathematically by the equation of Anderson and May¹¹:

$$R_0 = \beta \times D \times c$$

Where R_0 is the average of secondary cases generated by primary case (is > 1 in a rising epidemic, $= 1$ in a steady state situation, and is < 1 in an outbreak coming under control) and β is probability of transmission in a sexual partnership, D is the length of time a person is infectious and c is the

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number of new sexual partners within a time period.

While condoms and other prevention measures can reduce "β", and STD treatment can reduce "D", controlling "c" is important in an epidemic, where R_0 is greater than one. A few highly promiscuous individuals, such as prostitutes who frequent crack houses, can fuel an epidemic. Using this model, Oxman et al demonstrated that for a heterosexually spread epidemic of syphilis in a census tract of 11,000 individuals, spread was dependent on as few as 14 women, or 0.1 % of the population, who had at least 300 partners a year.¹² More often than not, this 0.1% of the population "cycles" in and out of correctional facilities.

Hence, diagnosing STDs and delivering treatment to those in the core group should be of the highest priority. While Rhode Island no longer tests marriage-license applicants for syphilis, one of the least cost effective means of case finding, there may not yet be efforts applied to every STD proportional to risk. Over 50 years ago Surgeon General Dr. Thomas Parran sought to control STDs by contact tracing—quizzing each infected individual as to sexual contacts, testing these people, treating if necessary, etc., in linear fashion.¹³ Newer concepts have incorporated social network therapy—going beyond an individual's sexual contacts to include social contacts who may be engaged in the same destructive behavior.¹³ If the incidence of a certain STD is rising or remains constant in a jail setting, investigational efforts are warranted at this site.

The sheer number of people passing through the doors of a correctional facility represents not only an opportunity but a challenge. With an average length of stay in RI for those awaiting trial of only 8.2 days, correctional health services must identify and treat those infected rapidly. By preventing delays, such as with decreasing the turnaround of syphilis testing, the effectiveness of programs can increase several fold.^{14,15} Rapid identification of asymptomatic juveniles with suppurative STDs has been achieved in the Los Angeles juvenile detention halls by use of the LCR urine testing.⁵ Funding new methods for STD control remains the greatest obstacle to their availability.

CONCLUSIONS

Ignoring the population "hidden" behind bars may prevent effective control of sexually transmitted disease in a community. Like many other states, Rhode Island has fortunately witnessed a decrease in the rates of syphilis, chlamydia and gonorrhea over the past few years. Yet, without an effective vaccine for HIV, efforts to reduce endemic levels of these infections may be a significant protection against co-transmission of HIV. Funding to target the incarcerated population in the state's strategy of reducing the burden of sexually transmitted disease is money well spent.

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The Economic Cost of Strict Syringe Control

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The epidemics of human immunodeficiency virus (HIV) and injection drug use (IDU) in the United States are closely linked: one-third of all AIDS cases in the United States are attributed to injection drug use.^{1,2} Most of these HIV infections are the result of multi-person use of injection equipment or "sharing" of syringes, which occurs when sterile syringes are scarce.³ They are scarce because syringe possession and prescription laws and pharmacy regulations restrict access to sterile syringes in an attempt to curtail illicit drug use.⁴ Recently, recommendations have been made to remove these restrictions, based on public health concerns that they inadvertently contribute to the spread of blood borne pathogens.⁵

Rhode Island syringe possession laws are among the strictest in the country. Possession of a syringe is a felony punishable by up to five years imprisonment and \$3,000 fine. Rhode Island also has among the highest proportion of AIDS cases linked to IDU and has the highest reported rate of syringe re-use among IDUs.^{2,6} We examine Rhode Island's state expenditures for detaining individuals prosecuted for syringe possession.

METHODS

Statistics on illicit drug use in Rhode Island from 1994 to 1996 were provided by the Rhode Island Criminal Information System (CRIS). The CRIS reports include data on arrest charge, arrest date, disposition, sentence and time served. Data on the number of individuals arrested, convicted, and incarcerated for violation of syringe possession laws were collected. The total years served by these individuals was multiplied by \$35,000, the cost to incarcerate one individual for one year in Rhode Island, in order to calculate incarceration costs. Indi-

viduals who were incarcerated because of parole violation resulting from syringe possession were not counted, as this information was not available.

RESULTS

Between 1994 and 1996, needle and syringe arrests accounted for 10% of all drug possession arrests and 7% of all drug possession-related convictions in Rhode Island. Many people arrested for syringe possession were not convicted on that charge. (Table 1) Fifteen percent (108/731) of those who were arrested were incarcerated for syringe possession. The mean time served for individuals who were incarcerated for infraction of syringe possession laws was 13 months.

Although only 15% of violators of the syringe possession law are incarcerated for this offense, the law results in great cost to Rhode Island taxpayers. During this three year period, an accrued cost of \$4,156,251 was spent to incarcerate individuals who violated syringe possession laws.

Abbreviations Used:

CRIS	Rhode Island Criminal Information System
HIV	human immunodeficiency virus
IDU	intravenous drug use

DISCUSSION

We examined the easily ascertainable costs associated with regulations on syringes - a small part of the total costs. We did not look at social, public health or medical costs, or human suffering associated with these laws. Nevertheless, we found significant economic costs (over \$4 million) to Rhode Island taxpayers. This underestimates the true cost, because it omits expenses related to court procedures and law enforcement, as well as prison time served for parole violations due to charges of syringe possession. Connecticut repealed syringe laws in 1992, allowing the legal purchase and possession of syringes without a prescription.⁷ Syringe sharing among IDUs decreased from 71% to 29%.⁸ It is likely that this has led to a decrease in incident HIV infections

Table 1.
Arrests, convictions, incarcerations and costs of incarceration for possession of Needle/Syringe in Rhode Island 1994-1996

	1994	1995	1996	Total
Arrested	231	291	209	731
Convicted	133	162	129	424
Incarcerated*	43	39	26	108
Mean time served: months	10.6	17	11.6	13
Total time served: months (years)	457(38)	667(55)	301(25)	1425(118)
Total cost incarceration†	\$1,332,917	\$1,845,417	\$877,917	\$4,156,251

*Does not include individuals incarcerated for parole violations.

†Cost incarceration per year=\$35,000.

among IDUs, and a decrease in secondary infections among their sexual partners, and their children. However, the magnitude of this effect has not yet been determined. Similarly many infections with hepatitis B, hepatitis C, and other blood borne pathogens have been averted as well. The high costs of medical care for individuals with HIV, hepatitis B, and hepatitis C are largely borne by the state. It is reasonable to assume that the medical care costs due to a policy of syringe restriction in Rhode Island may be much greater than the costs associated with the criminal justice system.

There is no evidence to suggest that laws restricting access to sterile syringes decreases illicit-injection drug use. Rhode Island is an example of the ineffectiveness of these laws to discourage drug injection: Rhode Island has arguably as many intravenous drug-users as other states, yet Rhode Island has among the strictest syringe possession laws. A large body of evidence demonstrates that increasing the availability of syringes does not increase drug use.³ It does, however, decrease syringe sharing.³

Both to improve public health and to save money, pharmacists should be able legally to sell syringes. Preliminary results of a survey of 41 Rhode Island pharmacists suggest that 88% would sell syringes without a prescription if the laws were changed. Pharmacists are willing to play a critical role in HIV and hepatitis prevention. It is time to change the restrictive syringe policy that inadvertently promotes the spread of HIV and hepatitis viruses and imposes a large financial cost on the state of Rhode Island.

During the three year period, 1994-1996, an accrued cost of \$4,156,251 was spent to incarcerate individuals who violated syringe possession laws.



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The Need for Compassionate Care: HIV Infection Among Incarcerated Women

Anne De Groot, MD, and Sarah Leibel, AB

I have had the great honor to be the doctor to more than 400 women prisoners living with HIV - learning more from this experience than I have learned in all my medical texts, in all my travels, and from all my teachers. Looking at the world through the prisoners' eyes has forced me to become their advocate.

Women account for a small fraction of the prison and jail population nationwide, 7% and 11% respectively,¹ yet incarcerated women are disproportionately affected by human immunodeficiency virus (HIV). The numbers are staggering: at the end of 1995, 15% of female state prison inmates in the Northeast United States were known to be HIV seropositive, compared to 8% of male state inmates for the same region. From 1991 to 1995, the number of total male state inmates infected with HIV increased 28%, while the number of female state prison inmates infected with HIV rose 88%, a rate more than three times faster than that of men.² These figures confirm the need to address the rapidly expanding population of HIV seropositive incarcerated women.

Between 1992 and 1996, I helped establish an HIV clinic for HIV-positive women incarcerated at Massachusetts Correctional Institution at Framingham. During that period, on average, one in five women-inmates was HIV positive. The seroconversion rate was between 7 and 16% per year.

WHY ARE INCARCERATED WOMEN PARTICULARLY VULNERABLE TO HIV INFECTION?

Incarcerated women are disproportionately affected by HIV compared to incarcerated men and non-imprisoned populations of the United States.

The reasons are as follows:

First, incarcerated women are more likely than men to be serving time for a drug offense: The Massachusetts Department of Corrections reported in 1996 that 35% of female offenders were convicted of drug related crimes, compared to 19% of male offenders. Frequently, income-producing nondrug charges such as burglary, larceny, sex work and fraud obscure high numbers of drug-addicted women offenders who have acted to support their own drug habits,³ or their partners'. Second, many incarcerated women have traded sex for drugs or money, whether or not they are charged with prostitution.⁴ While not all women who engage in sex work are involved in high risk sexual

activities, addiction and poverty may make women who exchange sex for drugs or money particularly disempowered in their ability to negotiate safer sex practices with clients and intimate partners.⁵ Third, the disproportionate affect of HIV/AIDS on women of color⁶ and the disproportionate representation of women of color in correctional facilities⁷ may contribute to the high prevalence of HIV/AIDS among incarcerated women. Fourth, many incarcerated women have experienced childhood sexual abuse, which places them at increased risk of HIV infection. Finally, women are at a greater risk of contracting HIV through heterosexual intercourse than men.⁸ Inextricably linked to these enumerated risk factors are conditions of poverty and subordination, amidst racial and gender disparities in power that heighten their susceptibility to HIV infection.⁹

As I spoke with patient-prisoners about their HIV and the risks that they routinely took in their lives and in their work, I was struck by one thing: these women did not care what happened to them. I found it difficult to convince them to "live well" with HIV—to take their medicine, to prevent further exposures to HIV, to stay off drugs. These women, who seemed so tough and ready to fight in many ways, did not hold themselves in high esteem. They lacked the belief that their own bodies were "holy" or "sacred"—so it didn't matter if they shared needles or had sex with HIV-positive partners.

CHILDHOOD SEXUAL ABUSE AND HIV

Dr. Sally Zierler, who had studied a group of HIV negative Rhode Islanders, found that women who took the most HIV risks and were most likely to convert to HIV positive had a history of sexual or physical violence.¹⁰

In collaboration with Dr. Zierler, Jessica Stevens (a Brown undergraduate) and I asked the women in my prison clinic about their childhood sexual abuse (defined as abuse prior to the age of eighteen). The proportion of women reporting such abuse was approximately one in four among HIV negative women and one in two among HIV positive women incarcerated at Framingham.¹¹ For both groups, the most common perpetrator was a family member. Women who had a prior history of childhood sexual abuse were more likely to have used injection drugs, to have participated in sex work, and to have had unprotected sex; they were more likely to report all three risk behaviors than women who had no prior history of sexual abuse. A history of childhood

sexual abuse was also predictive of HIV infection: women who had been sexually abused as children were almost three times more likely to be infected with HIV than women who were not sexually abused as children.

We observed a disturbing association between the violence that is done to these women by their family members, by their intimate partners, by the clients with whom they exchange sex for money or drugs, and the violence that they do to themselves. As a result of the violence that they do themselves, they are incarcerated. They are disempowered when it comes to protecting themselves against HIV: they do sex work to put food on the table. They are sexually active with men who refuse to tell the truth about their HIV infection or wear condoms. They use drugs to quiet the demons that have been following them since they left the homes where they were physically, emotionally, and sexually abused.

Most recently, I have provided care to women living with HIV infection at the York Correctional Institution in Niantic, Connecticut, and the Hope Center Clinic at Memorial Hospital in Rhode Island, where I am continually reminded of women's risks. I just saw another woman, recently diagnosed with HIV, who had her first child (by her father) at age twelve. She was transferred to the so-called "mental health" unit at the prison, for beating her head on the concrete floor. This woman who was so bent on self destruction was all of 25 years old. She looked and acted like the child she was when her father raped her.

There are other stories about these women's struggles to survive.

Another patient still cannot escape the sexual advances of her father, even though she is 30 years old, and has AIDS. Another patient saw her mother beaten to death. At age 15, another married a man who kept her locked in the house and beat her daily for over ten years. When he did let her out, and she returned, he would smell her undergarments to see whether she had had an affair on the way to the corner store; just to be sure, he would beat her again. Why was she in prison? Because he brought her home HIV infection and that was just one burden too great to bear. She tried to kill him. Another woman was sold, at the age of 12, for crack cocaine. This was the life that she and her sister knew until they knew better. She said there was never any food in the house, that her mother sold the food stamps, that she and her sister would hoist up her son and her baby brother (both the same age) on their 12-year-old hips and go out to the market to steal food to eat.

WHAT SHOULD BE DONE TO HELP REDUCE INCARCERATED WOMEN'S RISK OF CONTRACTING HIV?

The women in prisons nationwide are the highest risk population in this country. Efforts to decrease HIV infection and to prevent morbidity and mortality should focus

on them. Rhode Island's correctional system offers a good model for addressing the high prevalence of HIV infection among incarcerated women by providing compassionate and comprehensive HIV care. Unfortunately, this is the exception rather than the rule. We need to continue building HIV prevention programs and establishing a standard of medical care for HIV positive incarcerated women throughout our nation's correctional facilities.

Compassionate care must incorporate HIV treatment, HIV prevention and thorough discharge planning. HIV treatment efforts should include: empathic and specialized HIV health care providers, case managers and counselors, who work with patients to improve adherence to complicated drug regimens; confidential and voluntary HIV testing of all women inmates; voluntary HIV testing and antiretroviral therapy for pregnant incarcerated women;

state-of-the-art therapies, including triple drug therapy, post-exposure prophylaxis (PEP), viral load monitoring, and access to clinical trials; facilitation of adherence to medication guidelines through keep on person (KOP) programs, flexible medline hours, access to medications during court trips and timely transfer of medications and medical records; and gynecological care, including on site colposcopies. Most critically, this care should be provided by

informed, compassionate persons.

Given that incarcerated women are the fastest growing HIV-positive population, prisons permit vital HIV prevention efforts, which should include: workshops that help develop safer sex negotiation skills; support services that address drug use, sexual abuse, domestic violence and the resultant psychological trauma; and vocational training. These programs should develop educational skills and psychological strategies to help women protect themselves against addiction, abuse and HIV infection. In addition, harm reduction strategies such as making condoms, dental dams, clean needles and bleach kits readily available to women inmates should be considered to reduce HIV transmission within prisons.

Prevention efforts begun during incarceration must continue after release. Continuity of medical care for HIV seropositive women is dependent on coordination of clinic access, drug treatment programs, safe housing, and social services that provide child care. Risk reduction efforts that begin in correctional settings must be continually reinforced through similar programs for HIV seronegative women upon their release. The paucity of vocational and educational services inside correctional facilities and of shelters and hospices outside frequently forces released prisoners back into unsafe environments, where they risk relapse into crime. Beyond coordination of shelter and medical care access, discharge planners must facilitate educational development and skills-building. Alternative sentencing options can help these women do what drugs, racism, poverty, familial violence and social disenfranchisement have prevented them

The same struggles for survival that put them at risk of arrest put them in the path of HIV.



from doing: build self-esteem, marketable skills, healthy living spaces and stable, productive lives.

Behind prison walls and jail cell bars lies a virus that is killing women, killing their partners, killing their children. If we do not address HIV infection among incarcerated women, if we do not pay attention to the standard of care, we will lose generations. Knowing these women, it is clear to me why HIV infection features large among women-prisoners. The same struggles for survival that put them at risk of arrest put them in the path of HIV. Compassionate and comprehensive provision of medical care and support services is necessary if we are to reduce the spread of HIV transmission, decrease HIV/AIDS related mortality and nourish the positive development of incarcerated women.

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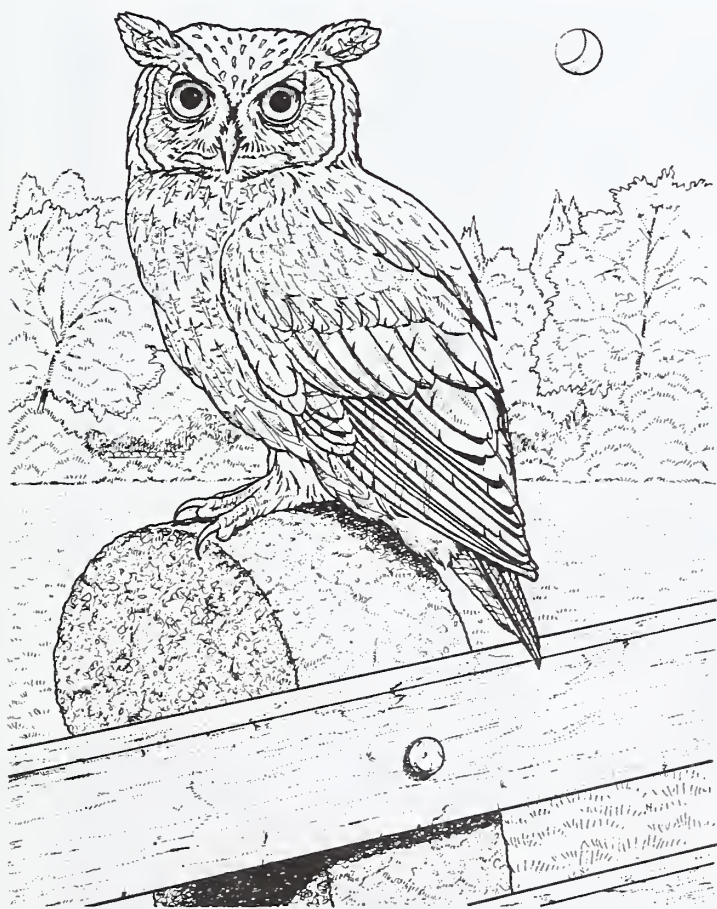
THIS CONTRIBUTION IS ADAPTED FROM A PRESENTATION TO MEDICAL STUDENTS AT BROWN UNIVERSITY ON APRIL 24, 1998.

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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Images in Medicine

Frank J. Schaberg, Jr., MD

The patient is an 84 year-old man admitted as an emergency for large bowel obstruction. Plain films were consistent with an obstruction at the level of the sigmoid colon. A CT scan was obtained which confirmed this.

After resuscitation, the patient underwent laparotomy for large bowel obstruction thought to be secondary to diverticular disease. Gross findings at surgery were consistent with this.

Several days following surgery the pathologist called to ask the surgeons if they were aware that the patient had a chicken bone in the sigmoid colon. Subsequently, the CT was reviewed; and what was originally thought to be a streak of contrast in the inflammatory mass in the sigmoid colon was clearly identified as the cause of his perforation and obstruction.

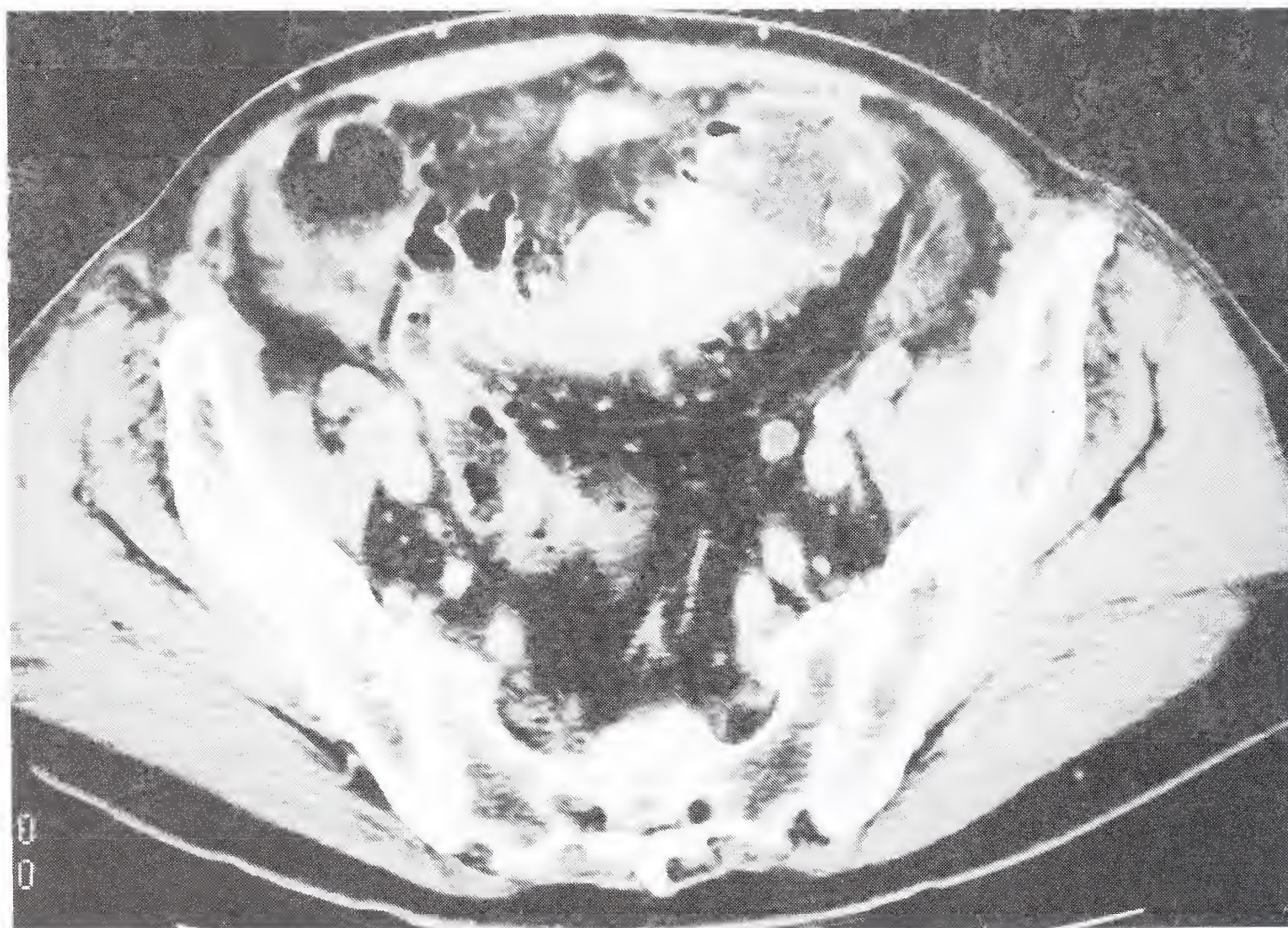
Frank J. Schaberg, Jr., MD, is Surgeon-in-Chief, Memorial Hospital of Rhode Island.

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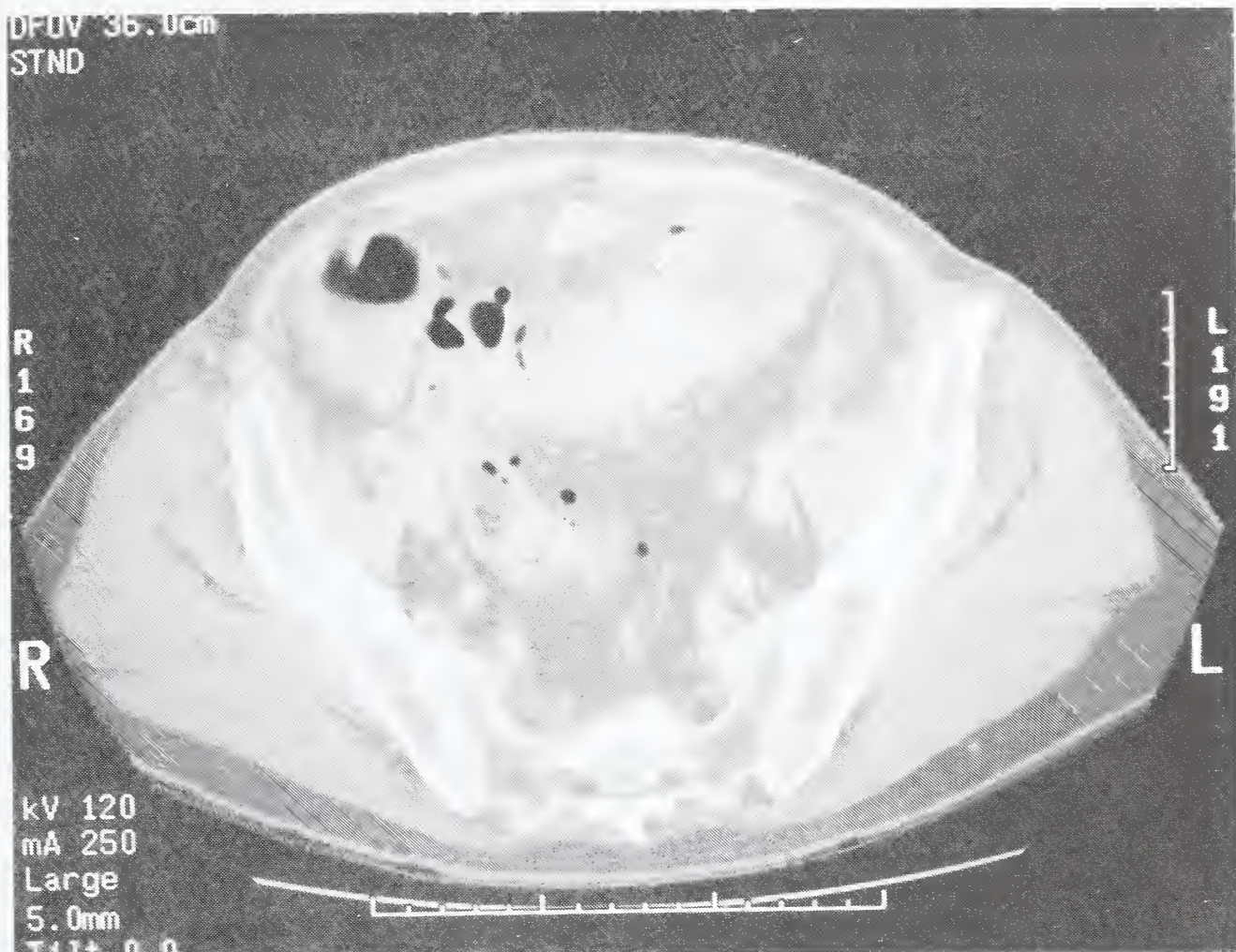
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The Creative Clinician is a regular feature in *Medicine & Health/Rhode Island*. If you have an interesting case you would like to share, contact: Anthony Mega, MD

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CT scan of the pelvis demonstrating a chicken bone in the obstructing inflammatory sigmoid mass.



CT scan of the pelvis demonstrating a chicken bone in the obstructing inflammatory sigmoid mass.



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**Rhode Island
Quality Partners, Inc.**

Edward Westrick, MD, MS

Health Care Quality Improvements in Rhode Island Diabetes Mellitus

Diabetes Mellitus (DM) is a common, complex, chronic disease with many serious but preventable long-term complications. As such, DM has become a tracer condition for the evaluation of health care quality. This is being driven by forces at the national level, including the HCFA, the NCQA, the ADA, and others. Here in Rhode Island there are a number of health care quality improvement projects underway and in the planning stages. This month's column will update you on national and local efforts to improve care for patients with DM.

DM afflicts about 10% of the adult population. There are significant morbidity and mortality due to acute and chronic complications. Quality improvement efforts currently focus on the prevention of chronic, not acute, complications of DM. Chronic complications can be divided into microvascular and macrovascular categories.

MICROVASCULAR COMPLICATIONS

Microvascular complications can be prevented through improved glycemic control, early identification of the complications, and prompt intervention when identified. These include retinopathy, nephropathy, and neuropathy. The DCCT demonstrated that progression of disease can be delayed by improved glycemic control in patients with Type 1 DM.¹ There is good reason to believe that this holds true in Type 2 DM as well.²

Diabetic retinopathy is the leading cause of new cases of blindness in adults.³ Early detection requires screening of asymptomatic individuals. An annual dilated funduscopic examination by an eye care professional has arguably become a standard of care in DM. Once identified, diabetic retinopathy should be followed until surgical intervention is indicated.

Diabetic nephropathy is the leading cause of end stage renal disease. Progression of diabetic nephropathy can be delayed by early treatment with ACE Inhibitor therapy and control of blood pressure. Early detection of diabetic nephropathy requires screening of asymptomatic individuals. Urinalysis for protein, microalbuminuria testing, and renal function testing are part of the screening strategy for

Abbreviations Used:

AAFP	American Academy of Family Physicians
ACEI	angiotensin converting enzyme inhibitor
ACP	American College of Physicians
ADA	American Diabetes Association
DCCT	Diabetes Control and Complications Trial
DM	diabetes mellitus
DQIP	Diabetes Quality Improvement Project
FACCT	Foundation for Accountability
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HEDIS	Health Plan Employer Data and Information Set
JNC	Joint National Commission
LDL	low density lipoprotein
NCQA	National Committee for Quality Assurance
RIQP	Rhode Island Quality Partners.
VA	Veterans Administration

this condition.⁴

There is no well-established intervention for preventing diabetic neuropathy. However, there are ways of preventing and treating its manifestations. Foot ulcers are a manifestation of this neuropathy. Diabetic foot infections and ischemic disease of the lower extremities lead to amputations. Early detection of diabetic foot disease can be accomplished through regular examination of the feet. Examination using a 10-gram pressure applied by a small filament can detect early neuropathy. Some suggest referring patients so identified to a foot care professional.⁵

MACROVASCULAR COMPLICATIONS

Macrovascular complications are the major causes of mortality in patients with DM, but are not necessarily prevented through improved glycemic control. These complications can be prevented through aggressive modification of known risk factors for macrovascular disease. The long-term complications include primarily: cardiovascular disease, cerebrovascular disease, and peripheral vascular disease.

The known modifiable risk factors for these complications include hypertension, dyslipidemias, cigarette smoking, obesity, sedentary lifestyle, and high fat diet. DM is an unmodifiable risk factor (with respect to macrovascular complications) along with age, gender, and family history.²

Therefore, it is important to identify these risk factors and treat them aggressively in patients with DM. The JNC⁶ makes special recommendations for the treatment of hypertension in patients with DM. The target blood pressure is lower in patients with DM and in those patients with diabetic nephropathy, ACEIs should be the first line agent for the treatment of the hypertension because of their independent beneficial effects in slowing the progression of this condition.

Dyslipidemias are common in DM. Early detection can be accomplished by serum cholesterol testing. LDL goals will likely be lower in patients with DM due to the additional risk factor(s). Aggressive therapy with lipid-lowering agents should prevent myocardial infarctions and strokes.

Cigarette smoking is another atherosclerotic disease risk factor that is devastating in patients with DM. Smokers with DM are particularly susceptible to peripheral vascular disease requiring amputation. These individuals deserve enhanced effort in smoking cessation counseling.

Sedentary lifestyle, high fat diet, and obesity have a multifactorial relationship as risk factors. A low fat diet and regular physical activity cannot only help patients lose weight, but they reduce risk for atherosclerotic disease beyond their effect on obesity. Lifestyle modification is the cornerstone of care in DM.

National and local quality improvement projects, currently underway and in the planning stages, will focus on practices that prevent these microvascular and macrovascular complications

HEALTH CARE QUALITY IMPROVEMENT AND DIABETES MELLITUS


At the national level, the HCFA, the NCQA, the AAFP, the ACP, the VA, the FACCT, and the ADA have been developing a set of indicators to measure quality of care in DM at the plan level. This effort is called the Diabetes Quality Improvement Project (DQIP). By the fall of this year, these indicators should be in their final form and should be accessible on the ADA website (www.diabetes.org). The indicators will measure glycosylated hemoglobin testing practices, patients with highest risk glucose levels, blood pressures, eye exams, foot exams, proteinuria and dyslipidemia screening. It is anticipated that these will become the standard set of quality of care measures in DM.

At the regional level, 16 Peer Review Organizations in the Boston Region (Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, West Virginia, Washington, D.C., Puerto Rico, and the Virgin

Islands) are working together on projects to measure and improve practices in these same areas. We have agreed upon indicator measurement issues and developed some common interventions. Dilated fundusoscopic examinations, glycosylated hemoglobin tests, and office visits will all be measured at the patient level in this multi-state effort.

In January, RIQP launched the first project of its series in Rhode Island. This project seeks to reduce blindness due to diabetic retinopathy by increasing the asymptomatic screening rates for early identification of disease. Nationally, this aspect of care for patients with DM has become the most widely used indicator. It is part of the Health Plan Employer Data and Information Set (HEDIS) that health plans need to report in order to be accredited by the NCQA. A similar measure was recently used by the General Accounting Office (GAO) to measure this practice in Medicare beneficiaries. We have done some measurement in Rhode Island based upon more recent experience.

The HEDIS measure demonstrated that 37% of patients with DM have an annual dilated fundusoscopic examination.⁷ This is a national average of plans. The GAO report showed that in 1994, 42% of Medicare beneficiaries with DM were receiving this recommended service. At that time, according to the GAO report, Rhode Island beneficiaries were receiving this service somewhat more frequently, 48% in that year.⁸ More recently, RIQP analyzed Part B

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Medicare claims for 1996. During that year 60% received this recommended service. It does appear that practices are improving; however, there remains substantial room for further improvement.

In January 1998, Medicare beneficiaries with DM received postcards highlighting the importance of dilated fundoscopic examination in the prevention of blindness and coverage information by Medicare. Physicians who care for Medicare patients with DM received copies of this postcard along with a letter of support from the Rhode Island Medical Society, the Rhode Island Department of Health, the Medicare Carrier in Rhode Island (Blue Cross/Blue Shield), the Rhode Island Optometry Association, the Rhode Island Society of Eye Physicians & Surgeons, and the Diabetes Foundation of Rhode Island. This month, physicians will receive posters for display in their offices, reminding patients to think about dilated fundoscopic examinations. In September, an entire issue of this journal will be dedicated to Type 2 DM.

RIQP will tally the claims for this service and compare them with the same time periods in 1997 to evaluate the impact of these interventions. We welcome suggestions for other interventions that can improve practices in this project, and in other projects. Please feel free to contact me at RIQP by phone (401) 528-3250, fax (401) 528-3210, or e-mail ripro.ewestric@sdps.org.

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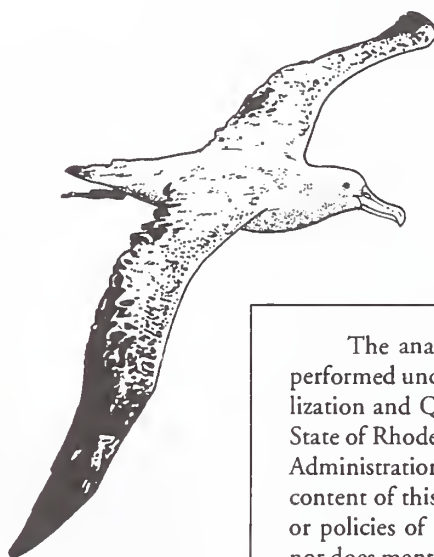
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CALL FOR AUTHORS

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.



AIDS Morbidity and Mortality in Rhode Island

Kai-Lih Liu, PhD, MPH, Paul G. Loberti, Jr., MPH, and Lucille Minuto, MEd, RN

Since the initiation of the Rhode Island AIDS case-reporting system in 1983, and through December 31, 1997, 1,758 AIDS cases were reported among Rhode Island residents. The year of reporting and the year of diagnosis are used to evaluate secular trends in the AIDS incidence rate. The year of reporting is determined by when a case is reported to the Department of Health; the year of diagnosis indicates the clinical onset of AIDS, as determined by evidence of a low CD4+ count and/or opportunistic diseases. Because of delays in reporting incident cases, the year of reporting may post-date the year of diagnosis.

The year of diagnosis is a more useful indicator to determine the trend of the AIDS epidemic over the years, in part because the AIDS case definition has been revised by the Centers for Disease Control and Prevention (CDC) three times since 1983. In 1985 and 1987, the AIDS surveillance case definition was revised to include opportunistic diseases (e.g., Kaposi's sarcoma, *Pneumocystis carinii* pneumonia) along with a positive HIV test. To increase the sensitivity of the surveillance system, the CDC expanded the definition in 1993 to include HIV infected individuals with less than 200 CD4+ T-lymphocyte cells/μL or a CD4+ T-lymphocyte count less than 14% of total lymphocytes, irrespective of clinical manifestation.

AIDS Incidence

The expansion of the AIDS case definition in 1993 dramatically increased the number of AIDS cases reported in Rhode Island. (Figure 1) Many cases with onset prior to 1993 only became reportable under the revised definition. Nevertheless, the number of cases diagnosed in 1993 was the largest for any year to date.

Based on year of diagnosis, the AIDS incidence rate in Rhode Island decreased annually between 1993 and 1996 and leveled off in 1997. (Figure 2) This trend suggests that the AIDS epidemic in Rhode Island is moving towards a stable endemic plateau, rather than a continuing decrease in AIDS incidence. In fact, Rhode Island had four more cases of AIDS in 1997 than in 1996, and additional cases diagnosed in 1997 may be reported.

AIDS Mortality

A significant point of optimism is the decreasing number of deaths among AIDS cases in Rhode Island since 1994 (Figure 2). This is consistent with the decreasing trend in AIDS deaths nationally. The AIDS surveillance data reveal a 33% drop in AIDS deaths in Rhode Island in 1996 from the previous year, and a further 32% drop in 1997. The magnitude of this decrease was not as significant as in some other places. For example, Maryland (43%) and New York City (48%) both reported larger reductions in AIDS-related deaths between 1996 and 1997.

Since the AIDS definition was expanded in 1993, a large proportion of AIDS cases have been ascertained based on the finding of a low CD4+ count without any opportunistic disease. It is expected that AIDS cases without an opportunistic disease will have a longer survival time than AIDS cases with opportunistic diseases (notably with *Pneumocystis carinii* pneumonia or Kaposi's sarcoma). This is consistent with the Rhode Island experience. In addition, the advances in protease inhibitor chemotherapy combined with aggressive and early case management of people living with AIDS have undoubtedly contributed to improved survival rates in the past two years.

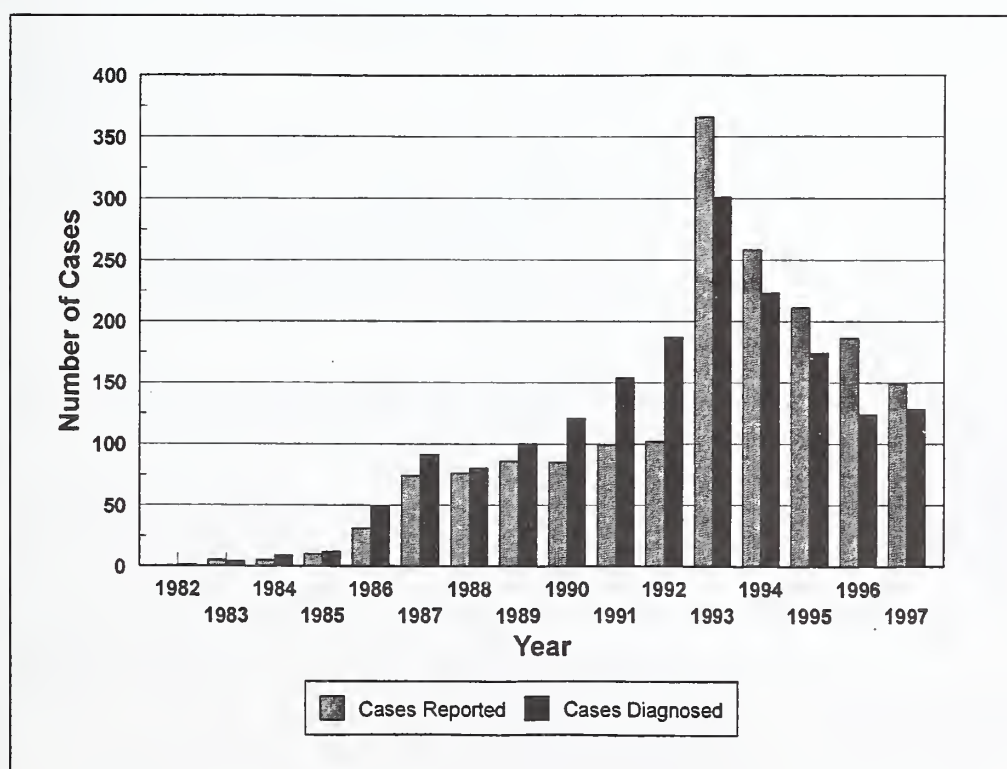


Figure 1. AIDS cases, by year of diagnosis and by year of reporting, Rhode Island, 1982-

AIDS case fatality rates are calculated for each year by the year of diagnosis in Figure 3. The annual AIDS case fatality rate is the number of deaths ever reported among AIDS cases diagnosed in that period (regardless of the year of death), divided by the total number of AIDS cases diagnosed in that period. The AIDS case fatality rate in Rhode Island has declined steadily, from 95% in 1989 to 8% in 1997. However, the case fatality rates for recent years may be underestimated because of incomplete ascertainment of deaths, especially for 1996-1998, and because of the earlier diagnosis of AIDS based on the CD4+ criteria.

Discussion

Since the FDA approved the protease inhibitor combination ("cocktail") treatment for HIV/AIDS treatment in 1996, AIDS mortality has significantly decreased, nationally

and in Rhode Island. This decrease suggests that AIDS is changing into a chronic illness from being an acute, fatal disease. However, critics argue that perhaps it is too early to declare victory for protease inhibitor chemotherapy. Many other factors may have contributed to decreases in AIDS case fatality rates; specifically, more aggressive detection, prophylaxis and treatment of opportunistic infections.

AIDS incidence statistics reveal that the epidemic is leveling off, but not significantly decreasing in Rhode Island. HIV prevention is still the critical factor in the formula to minimize the incidence of HIV and AIDS. The Rhode Island HIV Prevention Community Planning Group (RICPG) has continued to address the importance of prevention to combat any complacency that may be induced by decreasing AIDS mortality. The RICPG is a community-based partnership with the Rhode Island Department of Health to help guide the HIV prevention process in Rhode Island. Each year the RICPG produces a prevention plan and reports on prevention efforts. Through the combined efforts of an epidemiologic profile and needs assessment, the following target populations/risk behaviors have been identified as most in need of HIV prevention services:

- **injecting drug users**, their sexual partners, children and needle sharing associates;
- **women engaging in unprotected sexual intercourse**, especially African American and Latina women living in urban areas;
- **men who have sex with men**, especially HIV positive men who have sex with men, males under 21 years of age, and gay men of color;
- **youth**, including youth with sexually transmitted diseases, sexually active youth (especially African American and Latino youth), gay/bisexual youth;
- **HIV negative persons in prison**, in home confinement and recently released inmates and their partners;

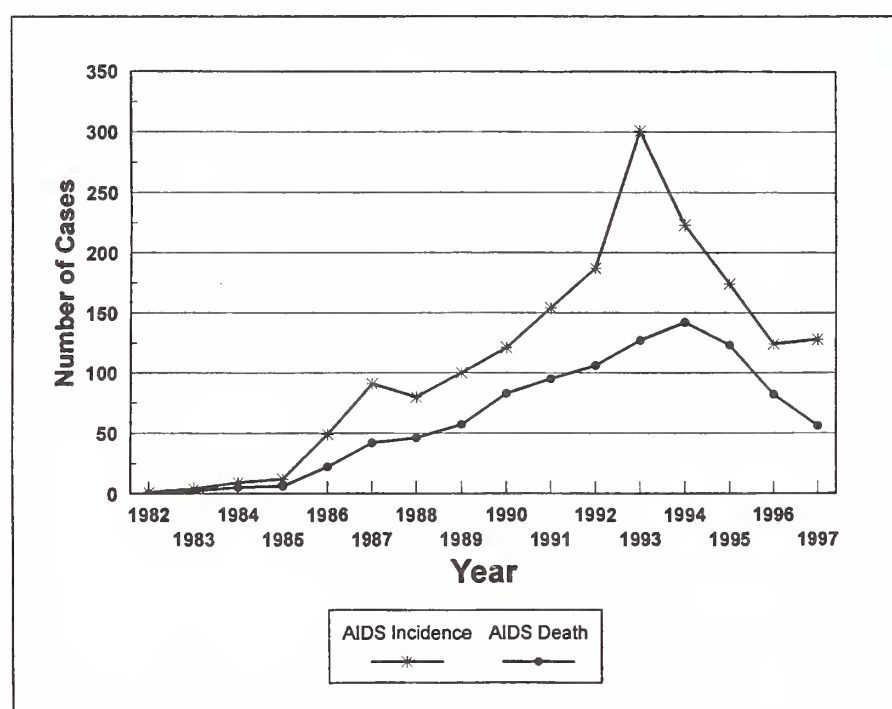


Figure 2. AIDS cases and AIDS deaths, Rhode Island, 1982-1997.

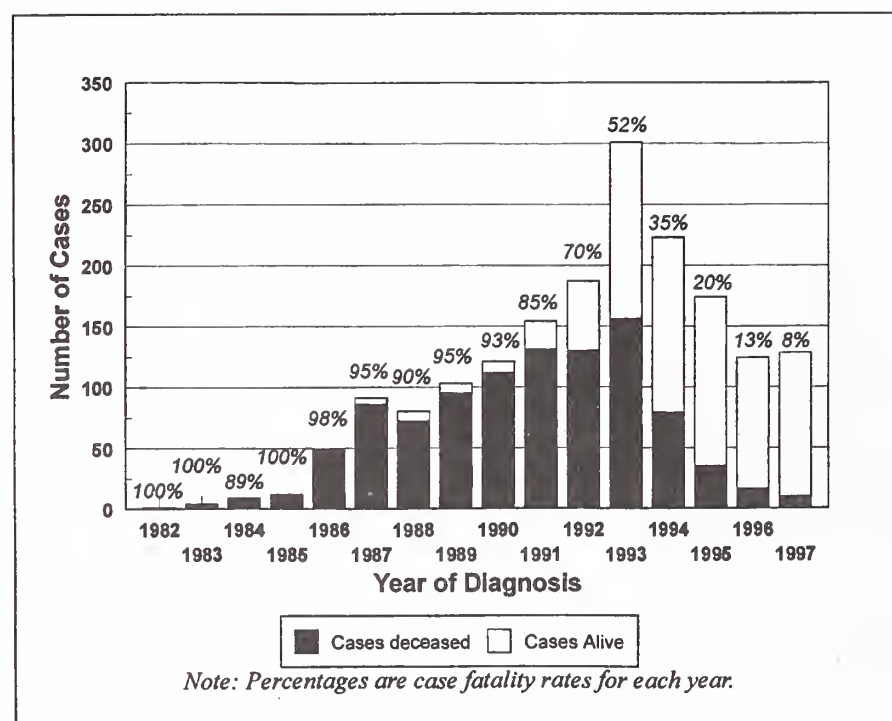


Figure 3. AIDS case fatality rates, Rhode Island, 1982-1997.

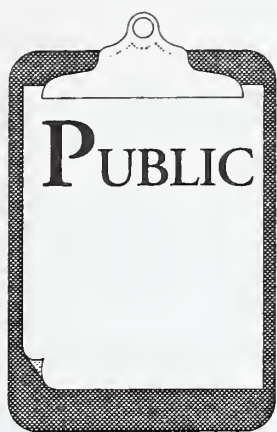
These target groups, highlighted in the 1998 HIV Community Prevention Plan, present the major focus of HIV prevention efforts in Rhode Island.

For the future, as AIDS mortality continues to decline nationally, we can expect an increased emphasis on HIV surveillance as the indicator to measure the scope and impact of this pandemic, and to guide our prevention planning and evaluation activities.

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Cancer Control Report Card: Rhode Island, 1998

John P. Fulton, PhD, and Dorothy Darcy, AS, CTR

Objective

The Rhode Island Cancer Registry, run collaboratively by the Rhode Island Department of Health (DOH) and the Hospital Association of Rhode Island (HARI), constructed a cancer control report card for Rhode Island, based on available state and national statistics, and referencing Healthy People 2000 cancer control goals.

Methods

Healthy People 2000 cancer control goals and statistics on available indicators of cancer surveillance, prevention, screening, incidence, and mortality were abstracted or calculated from four national publications^{1,2,3,4} and the Rhode Island Behavioral Risk Factor Surveillance System.

Current Rhode Island statistics on target activities, indicators, and rates were compared with past Rhode Island statistics, current United States statistics, and Healthy People 2000 cancer control goals to evaluate the State's progress toward reducing the burden of cancer among all Rhode Islanders. Progress towards Healthy People 2000 goals was evaluated.

Highlights

PREVENTION:

- Fewer adults smoke cigarettes.
- More adults exercise regularly.

SCREENING:

- More women ages 45+ get biennial Pap tests.
- More women ages 40-49 get biennial mammograms.
- More adults get annual rectal exams. Rhode Island exceeds the Healthy People 2000 goal for this screening activity.

SURVEILLANCE:

- The Rhode Island Cancer Registry meets all standards for the inclusion of Rhode Island data in the calculation of incidence rates for the United States

as a whole and for North America as a whole, as published annually in *Cancer in North America*.³

INCIDENCE RATES:

- Male lung cancer rates have plateaued.
- Male colo-rectal cancer rates have decreased.

MORTALITY RATES:

- Male lung cancer rates have plateaued.
- Colo-rectal cancer rates have decreased.
- Breast cancer rates have decreased.
- Male "all cancer" rates have decreased.

Concerns

PREVENTION:

- Fewer adults eat at least 5 servings of fruits and vegetables per day.
- More adults, especially men, are overweight, although Rhode Island is very close to the Healthy People 2000 goal for decreasing the prevalence of overweight among women.

SCREENING:

- Fewer women ages 18-44 get biennial Pap tests, but Rhode Island is close to achieving the Healthy People 2000 goal for cervical cancer screening in this age group.
- Fewer women ages 50+ get annual mammograms. In 1990, Rhode Island exceeded the Healthy People 2000 goal for screening mammography among women ages 50+.

INCIDENCE RATES:

- Female lung cancer rates have increased.
- Cervical cancer rates have increased.
- "All cancer" rates have increased.

MORTALITY RATES:

- Female lung cancer rates have increased.

Cancer Control Report Card, Part 1: Prevention and Screening Activities							
Target Activity	Yr 2000 Goal	BaseYr RI	LateYr All States	Base% RI	Late% RI	Late% Median State	Progress RI
● Decrease % adults smoking cigarettes.	15%	1990	1995	25.7	24.7	22.4	+
● Increase % adults getting regular leisure time physical activity.	30%	1990	1994	44.0	45.8	34.3	+
● Increase % adults eating five fruits and vegetables daily.	100%	1993	1996	25.5	24.1	NA*	-
● Decrease % adults overweight.	20%	1990	1995	23.9 ♂ 20.9 ♀	28.6 ♂ 21.6 ♀	30.6 ♂ 26.4 ♀	- -
● Increase % women ages 18-44 getting biennial Pap test.	85†	1991	1995	84.5	83.0	83.1	-
● Increase % women ages 45+ getting biennial Pap test.	85†	1991	1995	63.2	68.1	72.7	+
● Increase % women ages 40-49 getting biennial mammogram.	NA*	1990	1995	66.5	74.6	65.5	+
● Increase % women ages 50+ getting annual mammogram.	60	1990	1995	60.9	49.7	54.9	-
● Increase % adults ages 40+ getting annual rectal exam.	50‡	1993	1995	49.5	52.8	40.7	+

* NA = Not available. † Yr 2000 goal: Pap test every 1-3 years. ‡ Yr 2000 goal: fecal occult blood test every 1-2 years, adults ages 50 and over.

Cancer Control Report Card, Part 2: Surveillance; Cancer Registry Quality Control Indicators				
Target Indicator	% Goal*	Period	% RI	Progress RI
● Reduce the % of duplicate reports.	0.1	90-94	0.1	++
● Increase the % of completeness of case reporting.	90	90-94	97	++
● Limit the % of cases with data from death certificate only.	3	90-94	1.6	++

* Established by the North American Association of Central Cancer Registries

Cancer Control Report Card, Part 3: Incidence and Mortality Rates							
Target Cancer Rate (Cases or Deaths / 100,000)	Yr 2000 Goal	BaseYr RI	LateYr All States	Base% RI	Late% RI	Late% Median State	Progress RI
● Decrease incidence of lung cancer.	NA*	88-90	90-94	90.3 ♂ 40.6 ♀	89.9 ♂ 45.2 ♀	79.5 ♂ 42.0 ♀	+ -
● Decrease incidence of cervical cancer.	NA	88-90	90-94	7.4 ♀	9.3 ♀	9.4 ♀	-
● Decrease incidence of colo-rectal cancer.	NA	88-90	90-94	74.2 ♂ 46.0 ♀	67.1 ♂ 45.5 ♀	55.8 ♂ 38.9 ♀	+ +/-
● Decrease incidence of all cancers combined.	NA	88-90	90-94	441.0 ♂ 344.9 ♀	493.5 ♂ 361.4 ♀	485.1 ♂ 342.4 ♀	- -
● Decrease mortality from lung cancer.	53.0†	88-92	90-94	75.7 ♂ 31.4 ♀	75.4 ♂ 32.8 ♀	73.2 ♂ 32.8 ♀	+ -
● Decrease mortality from cervical cancer.	1.5	88-92	90-94	2.4 ♀	2.6 ♀	2.9 ♀	+/-
● Decrease mortality from colorectal cancer.	18.7†	88-92	90-94	28.2 ♂ 17.6 ♀	25.9 ♂ 16.3 ♀	22.4 ♂ 15.1 ♀	+ +
● Decrease mortality from breast cancer.	25.2	88-92	90-94	31.6 ♀	29.3 ♀	26.4 ♀	+
● Decrease mortality from all cancers combined.	175.0†	88-92	90-94	234.0 ♂ 147.9 ♀	226.8 ♂ 147.2 ♀	217.9 ♂ 141.7 ♀	+ +/-

* NA = Not available. Yr 2000 cancer incidence goals were not defined. † Yr 2000 cancer mortality goals were not defined by sex.

Discussion

Overall, Rhode Island is moving ahead toward the achievement of Healthy People 2000 cancer control goals. Smoking is down, exercise is up, cancer screening is generally up or strong, and we have begun to see decreases in cancer incidence and mortality.

That adult smoking is decreasing is especially heartening, as tobacco use causes almost half the cancers in the United States. In Utah, where the latest adult smoking prevalence is 13.2%, cancer incidence and mortality from all cancers combined is the lowest in the nation.^{2,3} Even though lung cancer incidence and mortality are on the increase among Rhode Island women, these trends will reverse, because of the downward trend in adult smoking (in women as well as men). Lung cancer rates among women should peak considerably lower than the lung cancer rates for men, because women never achieved the same smoking prevalence as men, despite the best efforts of the tobacco industry to develop the market among women.

Cancer surveillance in Rhode Island has been strengthened substantially by funding from the Centers for Disease Control and Prevention's National Program of Cancer Registries, which allows cancer registrars from the Hospital Association of Rhode Island to assist cancer registrars in the community with quality assurance functions aimed at increasing the completeness and accuracy of cancer case reporting.

That mortality from breast and colorectal cancer is down is consistent with the gains made in screening for these two diseases. The use of the annual rectal examination in Rhode Island is especially noteworthy, as it exceeded the Healthy People 2000 goal in 1995. Despite setbacks in the use of mammography attributable to Medicare's retrenchment in reimbursement for the procedure among women ages 65 and older, Rhode Island's breast cancer screening profile remains strong. The frequency of mammography use among women ages 40-49 is close to the highest in the nation. With support from their peers, families, and health care providers, women ages 40-49 should maintain this positive health behavior as they grow older. Mammography use should also increase substantially among women ages 50 and over, following Medicare's recent decision to reimburse annual mammography for women ages 65 and over, once again. Hopefully, Rhode Island's use of mammography among women ages 50 and over will quickly increase to its 1990 level (meeting the Healthy People 2000 goal) and beyond.

Nonetheless, certain concerns remain. The Rhode Island diet is not rich in fruits and vegetables, and the trend seems to be in the wrong direction. Perhaps related to this, the proportion of adults who are overweight has increased over time. Diet is difficult to change, and inter-

ventions to effect changes in diet can be costly. Nonetheless, we must persist in this effort. Balancing the Rhode Island diet would not only help prevent colorectal cancer, but would have salutary effects on cardiovascular disease, diabetes, and the disabling effects of overweight, especially among elders.

The incidence of cervical cancer has increased. Despite Rhode Island's strong showing with regard to use of the Pap test, we must screen more intensively. Theoretically, we can achieve zero incidence of cervical cancer through effective screening. Almost all cervical lesions develop slowly enough that biennial Pap smears should identify them as pre-cancerous infections or dysplasias.

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Dorothy Darcy, AS, CTR, is Director, Cancer Information System, Hospital Association of Rhode Island.





Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	December 1997	12 Months Ending with December 1997	
	Number	Number	Rates
Live Births	1,169	13,240	13.4*
Deaths	905	9,885	10.0*
Infant Deaths	(9)	(94)	7.1#
Neonatal deaths	(8)	(78)	5.9#
Marriages	405	8,072	8.2*
Divorces	284	3,162	3.2*
Induced Terminations	343	5,464	412.7#
Spontaneous Fetal Deaths	83	878	66.3#
Under 20 weeks gestation	(80)	(814)	61.5#
20+ weeks gestation	(3)	(64)	4.8#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	June 1997	12 Months Ending with June 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	244	3,404	343.8	3,923.5**
Malignant Neoplasms	201	2,496	252.1	6,595.0
Cerebrovascular Diseases	56	648	65.4	967.0
Injuries (Accident/Suicide/Homicide)	19	336	33.9	6,084.0
COPD	33	462	46.7	275.0**

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

Philately in Medicine

John Tierney

Queen Elizabeth I's Bout With Smallpox

"Smallpox... a disease that has ever been considered the scourge of the human race." – Edward Jenner

In October 1562, at the age of 29, Queen Elizabeth I (1558-1603) [Barbardos 1970-71, #66 B7] nearly died from a severe attack of smallpox [United Nations, 1978, #295]. The Council considered nominating the Earl of Huntingdon as her successor.

Elizabeth's advisors summoned the highly respected German-born physician, Dr. William Burcot, to the palace. Although the Queen's skin was

still clear, he told her, "My Liege, thou shall have the pox." [Guinea, 1970, #552].

Burcot's diagnosis angered the Queen, who was probably frightened that she might have smallpox. Even if she were lucky enough to survive a bout, she was at high risk of being badly scarred on her face. The Queen was so angered by his suggested diagnosis she said, "Have away the knave out of my sight."

Hours later, the Queen became incoherent, sinking into a coma. After midnight a rash appeared. Two men from the Court were sent on horseback to fetch Dr. Burcot. Still angry from his earlier encounter with the Queen, Burcot said, "By God's pestilence, if she be sick, there let her die."

A faithful servant then threatened to kill Dr. Burcot on the spot if he didn't do all he could to save the Queen. Speechlessly furious, the doctor mounted his horse and galloped off to the palace.



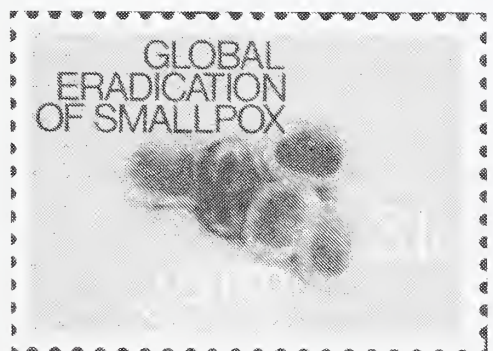
Dr. Burcot ordered a mattress to be put by the fire, wrapped the Queen in a great length of scarlet cloth, and held a drink to her lips.

Elizabeth gradually recovered, but she remained in her private apartment until all signs and symptoms disappeared.

The grateful Queen paid Dr. Burcot one hundred marks, gave him a plot of land in Cornwall, and presented him with a pair of gold spurs inherited from her grandfather Henry VII. She went on to rule for forty-one more years. And she wore heavy makeup, which masked the scars.

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NINETY YEARS AGO

❧ [JUNE, 1908] ❧

Jay Perkins, MD, of Providence, begins his essay on specific therapy in tuberculosis with this observation: "It is well within the memory of most of us when the diagnosis of pulmonary tuberculosis carried with it the administration of creosote and cod liver." The author enumerates the various medications that have had some measure of popularity since the lapse of creosote therapy, including the caccodylates, cinamic acid, formalin, antiseptic inhalants and Duffy's Pure Malt Whiskey. He then discusses the current enthusiasm for tuberculin therapy [calling it "tuberculin delirium."], including the written views of Koch, Virchow, Calmette and Trudeau. The author, personally, uses tuberculin only for diagnostic purposes and doubts that any therapeutic value may ensue from its use. Indeed, he claims that few now use it for any form of treatment except in cases of lupus. The discussion then describes the various forms of tuberculin, the means of their preparation and how they might be administered. A solution of tuberculin may also be employed diagnostically by topical application to the conjunctiva. [A positive reaction consists of local edema, congestion and even purulence.] With the widespread increase in the number of doubtful cases of tuberculosis in clinics, the author recommends the ophthalmic test as the surest and quickest means of distinguishing those simulating consumption and those truly afflicted by it.

M.J.O'Neil, MD, offers another paper on the diagnosis and treatment of tuberculosis. He begins by observing that until ten years ago there was little progress in the diagnosis or manage-

ment of the disease. While acknowledging the importance of sputum examination for the acid fast bacillus, he deplors the quasi-religious reliance upon it. There are many cases of consumption, he declares, with negative sputum examination. What early symptoms should the practitioner seek? The author stresses the importance of languor and excessive, inappropriate, fatigue as the earliest of signs. Next in importance are anorexia, unaccounted for episodes of minimal fever and some cough. He also stresses additional signs such as diaphoresis and insomnia. The new Roentgen ray machine represents a notable advance and is "a powerful ally in making an early diagnosis." There follows an extensive discussion on the merit of sending a consumptive patient to a sanatorium. In many cases such a decision weighs against the patient's best interests. With regard to drug therapy, beyond proper diet, the author believes that "the employment of drugs in tuberculosis must be guarded," and used only when absolutely necessary.

The Rhode Island Medical Society voted affirmatively on the following resolution protesting "enactment of any legislation which authorizes a body of non medical men ... to prescribe or care for any diseased conditions of the eye or its appendages."

Charles V. Chapin, MD, Superintendent of Health, provides his bimonthly report on the state of health in Providence. The annual mortality rate has dropped to 19.78 per thousand, a substantial decrease. There still are 199 deaths from tuberculosis per 100,000 population. And in the preceeding few months 74 cases of scarlet fever [with 7 deaths], 98 cases of diphtheria [with 12 deaths] and 161 cases of measles [with 20 deaths.] No case of rabies since January 6th of the current year.

FIFTY YEARS AGO

❧ [JUNE, 1948] ❧

Samuel A. Levine, MD, of Boston, marks the one hundredth anniversary of the founding of the Providence Medical Society by presenting a learned paper comparing the inadequacies and accomplishments of medicine in 1848 and 1948. He uses for his comparisons the pages of the *Boston Medical and Surgical Journal* as a guide to the capabilities of the profession at these two years. He concludes: "In a word, the responsibility of the physician is perfectly tremendous nowadays as compared to a hundred years ago." He specifically compares the attitudes, resources and capacities in such clinical phenomena as profound anemia, abdominal swelling and cardiac murmurs to illustrate how truly far the profession has advanced.

Aaron T. Beck, MD, reports a case of profound prerenal azotemia, resulting from vomiting, in a 45 year-old female. Following a subtotal gastrectomy for stenosing duodenal ulcer, the patient made a favor-

TWENTY FIVE YEARS AGO

❧ [JUNE, 1973] ❧

The lead article, by Jean K. Ashba, MD, and Milton W. Hamolsky, MD, discusses tuberculosis. The authors summarize verified cases of tuberculosis with neither a positive chest X-ray nor positive sputum examination for acid fast bacilli. They also discuss the reactivation of quiescent tuberculosis in immunocompromised hosts and the significance of a negative tuberculin test.

Patrick A. Broderick, MD, and Wayne A. Cotnoir discuss a technic whereby the placental site may be localized with the use of radio-active chromium tagged erythrocytes.

Paul B. Metcalf, Jr, MD, summarizes his studies comparing inpatient practices in hospitals affiliated with the Brown medical school and those not affiliated.

A. Paul Kelly, MD, and Bencel L. Schiff, MD, discuss the often confusing differentiation between scleredema and scleroderma.

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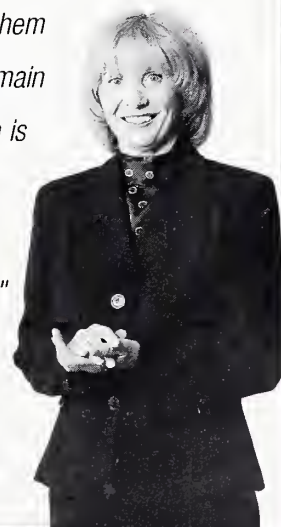


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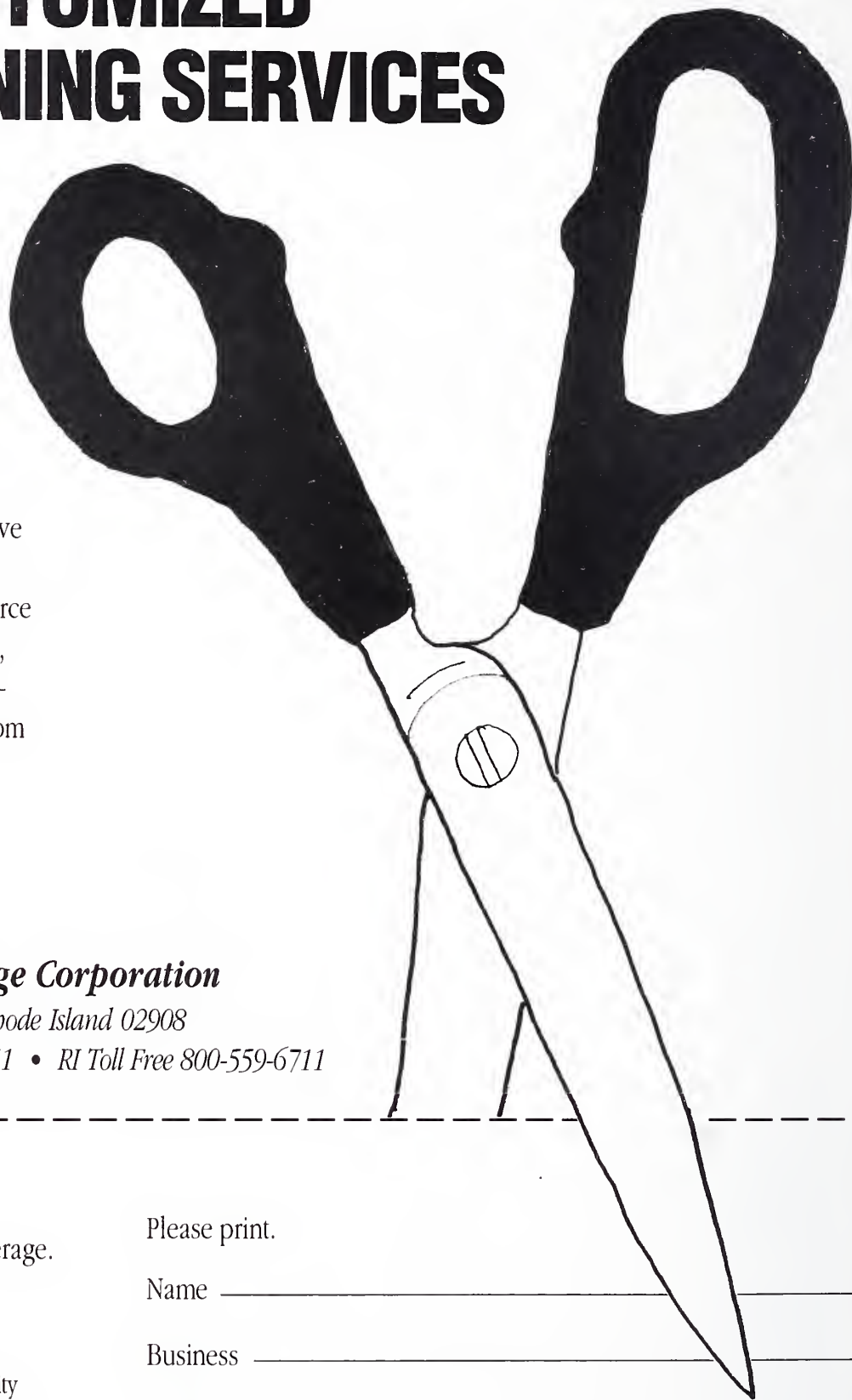
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The Rise and Fall Of Malaria



The annual number of new cases of malaria, globally, exceeds 300 million. Over a million children each year die of malaria. There is no effective vaccine to protect against this parasitic disease. The *Plasmodium* parasite now resists many of the anti-malarial medications; and the mosquito vector has become increasingly tolerant of the major insecticides. And yet, despite all of these grim realities, most of the temperate world has been freed of this scourge largely through the diligent employment of a number of effective public health interventions, measures which are not highly technical but which require, nonetheless, a great deal of uninterrupted effort, ingenuity and resourcefulness. Many of these effective measures were first learned on the Italian peninsula.

Malaria was no stranger to 19th Century Italians. Malarial fever had been so common in Rome that even the senior clergy regularly avoided the city during the mosquito-infested summer months. Shelley, a frequent visitor, had called the surrounding Roman countryside utterly pestilential, its "mortal dew" endured only by snakes

and worms. The Pontine Marshes southeast of Rome, lying between the Tyrrhenian Sea and the Apennine foothills, had once been a productive agricultural region during the early Roman Empire centuries. But these marshlands became ideal breeding sites for *Anopheles* mosquitoes, making the region so malarial that for centuries it was abandoned to the insects. Efforts to drain the swamps were begun during the reign of Trajan and continued intermittently by many popes. Significant reclamation of Latium [as well as malarial lowlands as far north as the Tuscany valleys] was not achieved, however, until the early decades of the 20th Century.

By the 1930's, the desolate, uninhabited, malaria-ridden Pontine swamps had finally been restored to fertile farm land for the cultivation of wheat and cotton. Draining the swamps, alone, was inadequate to suppress mosquito propagation since their larvae readily flourished in the drainage ditches. It then required a massive and time-consuming campaign of dusting the drainage canals with arsenical insecticides, covering residential windows with screening, and providing plentiful quinine to the residents. By 1935 the number of new cases of malaria, in this region, had dropped to 55,000, an immense and

impressive accomplishment.

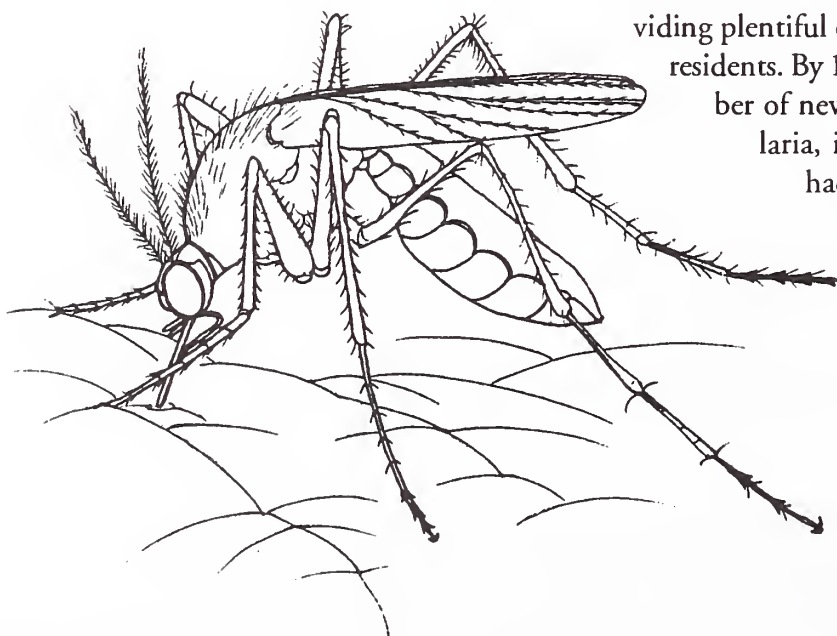
Italy entered World War II and the anti-malarial campaign was largely abandoned in favor of the country's military needs. By 1944, the number of new cases of malaria in the region had exceeded 400,000. Nature did not wait for the human conflict to be resolved.

This burden of malaria was not relieved until late 1944 when the Allied armies, having defeated the Axis forces, assumed temporary control of the civil government of Italy.

The Allied Control Commission confronted many problems, not the least of which was the massive resurgence of malaria. This posed three problems. First, malaria constituted a real threat to the Allied troops; second, untreated malaria was a debilitating and often lethal disease for the local civilians, diminishing domestic productivity particularly of foodstuffs; and third, there were no resources to reproduce the labor-intensive, prohibitively expensive antimalarial campaign which the Italians had successfully conducted earlier in the century. Accordingly, a quick and effective solution was sought.

Using the malaria-infested island of Sardinia as an experimental site, the U.S. Army sprayed a newly available insecticide [dichloro-diphenyl-trichloroethane, sometimes called DDT] upon the inner surfaces of every accessible house and barn as well as upon any visible body of still water where mosquitoes might breed. Within a few years, the island was rendered entirely free of malaria.

The carefully designed anti-malarial operation on the Italian mainland, under the direction of Dr. Albert Misiroli, Italy's leading authority on



mosquito-borne diseases, encountered many logistic problems but by 1951, only 392 new cases of malaria were encountered in all of Italy.

The astonishing and rapid success of DDT spraying was then repeated in western India, the Amazon basin of Brazil, Sri Lanka and numerous other places where insect-borne diseases were rife. Economists estimated that it cost between \$1 and \$2 for every case of malaria prevented in southern Europe. The ultimate economic benefits which accrued from a healthier student body and a stronger, less disease-ridden and more committed work force, however, were incalculable.

Since parasitic disease borne by insects [e.g., malaria, typhus, yellow fever, encephalitis, filariasis, sleeping sickness, etc] constituted the major cause of human morbidity and mortality in the 1950's, the arrival of DDT was considered a major public health

miracle. And indeed, by any criterion, the massive [and sometimes indiscriminate] use of DDT saved millions of human lives.

The secondary, unanticipated, problems generated by this mass intervention became apparent only later: The untoward results included the many toxic effects of DDT upon birds and other vertebrates; the carcinogenic residues infiltrating the food chain; the imbalance which developed between various insect species; and the nightmare of DDT-resistant strains of mosquito. But there were more subtle, and more enduring, ill effects. In Sri Lanka, for example, the sudden drop in mortality rate resulted in an unanticipated surge in population size without a parallel growth in

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supportive infrastructure [educational, health care, maternal, job opportunities, etc] to handle the augmented population.

Those who denounce the widespread use of DDT in the years immediately following World War II should balance the many human lives saved against the ecological havoc wrought before expressing their condemnation.

— Stanley M. Aronson, MD

Resident Physician Abstracts: Annual Scientific Meeting of the Rhode Island Chapter, American College of Physicians, 1998

The Twelfth Annual Joint Meeting of the Rhode Island Chapter of the American College of Physicians (ACP) was held at the Radisson Hotel on Tuesday, April 21, and Wednesday, April 22, 1998. Participation by medical residents in the Brown University and Boston University-affiliated hospitals was remarkable once again because of the quantity and quality of the submissions.

In total 13 abstracts were accepted for oral presentation and over 70 for poster presentation. The posters were displayed during the Tuesday evening session in the Plantations Ballroom. Physicians presented their work to their colleagues in a setting of food, drink and lively discussion. Once again, posters represented the work of resident physicians and faculty from hospitals in Providence, RI, including Memorial, Miriam, Rhode Island, Roger Williams and the Veterans Administration Medical Center. Poster presentations remained standing so that participants in the Annual Scientific Meeting could view the posters and continue to interact with the authors on Wednesday, April 22.

On that day, Dr. Cyr welcomed the group. Oral presentations were made; the abstracts are included in this issue. The College representative, Dr. Oscar E. Edwards, MD, FACP, gave a College update. This was followed by a presentation of medical informatics.

The Irving A. Beck Award was presented to Arthur M. Phillips, MD, FACP. This presentation was followed

by several Meet-the-Professor Sessions where experts from the Providence medical community interacted with residents and attending physicians to discuss difficult cases. This year the Meet-the-Professor attending physicians included Dr. Edward J. Wing, Dr. Norman Gordon, Dr. Oscar E. Edwards, Dr. Edward Martin and Dr. Leslie Robinson-Bostom.

The afternoon sessions included a discussion of alternative medicine, followed by further oral presentations. All participants agreed that these two days were a great success, and we look forward to next year's session.

— Fred J. Schiffman, MD, FACP

Fred J. Schiffman, MD, FACP, is Professor of Medicine at Brown University School of Medicine and Governor, American College of Physicians, Rhode Island Chapter.

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American College of Physicians, Rhode Island Chapter Associates Competition for Regional Meeting April 21 and 22, 1998

Pitfalls in Using the Urinary Legionella Antigen to Determine the Incidence of Legionella Pneumonia

Usha Panneerselvam, MD, and Philip O'Dowd, MD
Roger Williams Medical Center

Studies have established that *Legionella pneumophila* pneumonia (LPP) causes 2%-18% of hospitalized, community-acquired pneumonias (mean incidence=7%). LPP is the only pneumonia with a highly specific assay, the legionella urinary antigen LUA (Sn=80%, Sp=100%), allowing definitive diagnosis. Good urine is easy to obtain; good sputum is not. Many hospitalized pneumonia patients are tested with the LUA since LPP requires high dose erythromycin therapy (with associated morbidities) and would not be covered by the usual empiric antibiotic regimens.

It was our impression that LPP was uncommon in our hospitalized patients. We sought to estimate the incidence of LPP in Rhode Island by using the ULA positivity rate at our institution as an estimate of the maximum incidence of LPP. There were only 4 positive ULAs out of 495 processed at Roger Williams Medical Center in 1997 (0.8% incidence). Results at other Providence area hospitals confirmed a very low ULA positivity rate. Data from a national laboratory (116/5800=2%)

likewise showed a lower than anticipated positive test result rate. These data seemed to confirm our view that very few hospitalized pneumonias in Rhode Island can be attributed to LPP.

Record review, however, uncovered factors which undermine the validity of the method of estimating LPP incidence. First, many patients had multiple ULAs drawn during the same period. One patient had 5 negative tests. Over 10% of the ordered tests were duplicates. Second, ULAs were drawn on patients who did not have pneumonia. Patients with normal chest xrays and with abnormal chest xrays of other cause (e.g., CHF) had ULAs ordered. Third, after a "legionella outbreak" (2 cases), ULAs were obtained on that nursing home's patients with "respiratory symptoms and one failed treatment" without the requirement for CXR confirmation of pneumonia.

We conclude that inappropriate use of the ULA by physicians vitiates its value as an epidemiologic tool to estimate the incidence of LPP in Rhode Island.

Abbreviations Used:

AIIA	AI receptor antagonists	IDU	intravenous drug use
ABG	arterial blood gases	IST	International Stroke Trial
ACEI	angiotensin converting enzyme inhibitors	LPP	<i>Legionella pneumophila</i> pneumonia
AIDS	acquired immunodeficiency syndrome	LUA	legionella urinary antigen
BID	twice a day	MI	myocardial infarction
CAST	Chinese Acute Stroke Trial	MRA	magnetic resonance angiography
CHF	congestive heart failure	MRI	magnetic resonance imaging
CXR	chest x-ray	NMRP	National Medical Residency Program
CT	computed tomography	PFT	pulmonary function tests
EKG	electrocardiogram	RTA	renal tubular acidosis
ERCP	endoscopic retrograde cholangiopancreatography	RWMC	Roger Williams Medical Center
FEV ₁	forced expiratory volume in one second	ULA	urinary legionella antigen
GFR	glomerular filtration rate	VLDL/TG	very low density lipoproteins/triglycerides
HIV	human immunodeficiency virus		

Stroke Epidemiology at an Academic Community Hospital

Rafay Mehdi, MD, Bhanu Ravindrin, MD, and Philip O'Dowd, MD
Roger Williams Medical Center

The 1987 International Stroke Trial (IST) and the Chinese Acute Stroke Trial (CAST) provided detailed demographic and clinical data on 40,000 acute stroke patients and became the reference for stroke epidemiology and treatment. We reviewed the medical records of 200 consecutive acute stroke patients at Roger Williams Medical Center and compared them to IST/CAST in the fields of 1) age distribution, 2) vascular distribution, 3) time to presentation, 4) use of therapeutic anticoagulation and 5) short-term outcome.

Acute stroke accounted for fewer than 2% of RWMC admissions. The average admission rate (1994-1997) was 120 per year, or roughly 2 per week. Stroke admissions as a percent of total admissions declined annually for the past 4 years at a -8%/year rate.

Comparing RWMC data to IST/CAST:

The number of elderly (>80 years of age) was disproportionately high: RWMC=46%, IST=26%, CAST=28%.

The Anterior/Posterior/Lacunar vascular distribution was similar in all studies: RWMC=62%/14%/24%;

IST=64%/12%/24%; CAST=64%/6%/30%, with posterior events the least common in all. At RWMC about 25% of strokes were not assigned to a territory.

Atrial fibrillation was a frequent presenting rhythm in all three studies: RWMC=18%; IST=16%; CAST=7%.

Time to presentation was long in all three populations with very few stroke patients presenting within the 9-hour window of thrombolytic efficacy: RWMC=5%, IST=4%, CAST=4%.

The in-hospital death rate was comparable: RWMC=7.5%, IST=9%, CAST=3.6%.

Heparin was widely used as acute therapy in all vascular territories at RWMC and not preferentially for posterior events: anterior=57%, posterior=61%, lacunar=43%.

We conclude that the vast majority of stroke patients at RWMC and worldwide are ineligible for thrombolytics because of a late presentation and that the present widespread use of heparin in all distributions at RWMC is difficult to reconcile with the IST conclusion that heparin was of no benefit in any vascular distribution.

Alkaline Urine: Its Incidence and Differential Diagnosis

Amir Alizadeh, MD, and Philip O'Dowd, MD
Roger Williams Medical Center

Among the data obtained from the standard urinalysis, urine pH receives little attention. It was our hypothesis that infection with urea-splitting organisms would be the most common cause of an alkaline urine (pH>8). Such infections are clinically noteworthy because of an associated nephrolithiasis for which standard treatment regimens may not be appropriate. We reviewed the Roger Williams Medical Center urinalysis data for 1996 and 1997. There were 5164 specimens processed. Outpatient and emergency room samples accounted for the majority (4455/5164=86%). There were 709 inpatient specimens.

Alkaline urine was uncommon. Only 1 of 50 specimens (109/5164=2.1%) showed pH=8; pH9 was more uncommon, accounting for only 1 in 200 specimens (34/5164=0.66%). Of these 143 alkaline specimens, only 127 had an associated urine culture. Of the 109-cultured pH=8 urines, 33 grew proteus species (47%+ predictive value). Interestingly we identified 12 patients with proteus infection and a urine pH=7. The incidence of alkaline urine in the outpatient population (2.6%) was comparable to the inpatient population (3.8%). Proteus species infection, however, accounted for only 5% of inpatient alkaline urines while accounting for 44% of outpatient alkaline urines.

We reviewed the records of noninfected inpatients with alkaline urines to determine other causes. Bicarbonate or citrate administration caused alkaline urine. RTA, type 4, common in diabetics, caused alkaline urine. Carbonic anhydrase inhibitors, used in glaucoma, caused alkaline urine. There is a postprandial alkalinization of wine related to gastric acid shifts. Urine left to stand for more than 2 hours after collection (or sampled from a stagnant bag drainage system) may become alkaline due to ammonia formed by contaminating bacteria. Finally, metabolic compensation for respiratory alkalosis or for a metabolic alkalosis caused by vomiting can lead to an alkaline urine.

Urine alkalosis is an uncommon finding. We urge physicians to note its occurrence and consider the above differential diagnosis. If proteus species are cultured, and are refractory to short term antibiotics, the possibility of infected struvite stones must be considered, and ruled out. Most inpatients, however, have alkaline urine of other cause.



Hazardous Drinking in Primary Care Outpatients

*Stephen M. Scott, MD, Susan E. Ramsey, PhD, Michael Stein, MD, Michele G. Cyr, MD
Rhode Island Hospital*

The purpose of this study was to determine the current prevalence of hazardous drinking in a general internal medicine hospital-based clinic sample. Patients were asked to complete a 10-question screening questionnaire (AUDIT) upon presentation to the clinic. Of the patients approached (n=265), 50 were ineligible because they were non-English speaking, and 3 patients refused to be screened. Drinking information was obtained from 212 patients. The rate of hazardous drinking for the 3 months preceding the office visit, determined by AUDIT scores ≥ 8 , was 12.3%. Males (16.9%) and females (8.9%) displayed different rates of hazardous drinking ($p=.08$). Rates of hazardous drinking varied significantly across age groups ($p<.05$): patients aged 18-35 displayed a 10.9% rate, those aged 36-59 had a 17.3% rate, and patients 60 and over had a 3.8% rate. The 25 patients who screened positively for hazardous drinking were asked to complete a battery of questions regarding substance use and health. The hazardous drinkers reported a mean of 20.8 standard drinks per week, and a mean maximum number of drinks per day of 13.2. The hazardous

drinkers were at various stages of readiness to change their drinking behavior: 12% had no thought of changing, 40% felt they should consider changing or should make a change in the future, and 48% reported that they were starting to think about how to make a change or were already taking action to change. Thirty-six percent of the hazardous drinkers reported using illicit drugs in the previous 3 months: 24% reported cannabis use, 20% cocaine, 20% barbiturates, and 8% opiates. No one reported using amphetamines, hallucinogens, or inhalants. This study highlights the high rate of hazardous drinking among primary care outpatients and the willingness of patients to discuss their drinking. The majority of the hazardous drinkers were willing to consider making a change, either at the present time or at some point in the future. Therefore, intervening with these individuals could significantly impact their drinking. Concomitant drug use is prevalent among hazardous drinkers and should also be addressed in the course of a hazardous drinking intervention.

Communication Between Medical Students and Residency Programs in the Match

*Laura Obbard, MD, Ari Silver-Isenstadt, MD, Andrew Nowalk, PhD
Rhode Island Hospital*

During the course of the National Medical Residency Program (NMRP) matching process, applicants and residencies communicate through an application process, during an interview, and then with thank you letters and follow-up phone calls. NMRP materials provide guidelines for this communication: each party may express interest in the other; references as to how applicants or programs will be ranked should be avoided; and neither party may ask the other for a commitment before the match. Yet it is unknown what percentage of students communicate with residencies, or what effect this communication may have on student rank lists.

Questionnaires were sent to a random sample of 4000 fourth-year medical students immediately following the 1996 match. The questionnaires explored student attitudes toward the match, communication with programs during the match process, and ranking strategies and outcomes. Of 631 responses, 596 came from students participating in the match. Of those 596 students, 563 matched in the first round of the match, and 33 students (5.5%) did not (similar to the national percentage of 7% unmatched students).

Four hundred and thirty-four students (73%) reported that they had written or had personal communication with residency programs prior to the match, suggesting how they would be ranked at a program. Of those students, 112 (25%) then moved programs higher on their rank lists based on that information. Thirty-eight students (9%) answered affirmatively to the question: "Did any program ask you for a commitment before the match?" When comparing students who did and did not match, more of the matched students communicated with programs than the unmatched students (74% vs. 57%). Yet a higher percentage of the unmatched students proceeded to adjust their rank lists based on this communication (58% vs. 24%).

These results suggest that the majority of medical students communicate with residency programs after interviews, that some students then adjust their rank lists based on this communication, and that not all communication is within NMRP guidelines. Future research is needed to determine if this communication ultimately influences the matching process.

Substance Abuse is Responsible for Most Pre-AIDS Deaths Among Women with HIV-Infection in Providence, RI

Eleftherios Mylonakis, MD, Polyxeni Koutkia, MD, Josiah D. Rich, MD, Karen T. Tashima, MD, Teresa C. Fiore, Timothy Flanigan, MD, Charles C.J. Carpenter, MD
The Miriam Hospital

Advances in antiretroviral therapy have revolutionized our treatment of HIV infection, making it even more important to evaluate non-HIV related causes of mortality, such as substance abuse.

The aim of our study was to evaluate the impact of substance abuse on the pre-AIDS mortality among HIV-infected women. We reviewed all the medical records in a cohort of HIV-infected women who received care at our institution between 1988 and October 1997.

We identified 100 women who died. Data were available in 99 patients. Among them, 77 (76%) had a background of IDU. Eighteen patients (18%) died before developing AIDS (mean and median CD₄ count 584 and 548 cells/mm³, respectively). Fourteen of those deaths were related to substance abuse: narcotic drug overdose (10), en-

docarditis related to intravenous drug use (1), cirrhosis due to alcohol abuse complicated by variceal bleeding (1), alcohol induced pancreatitis (1) and homicide related to narcotics (1). The other four deaths, probably not related to substance abuse, occurred due to: motor-vehicle accident (1), malignancy (1), brain hemorrhage (1), and acute myocardial infarction (1).

Substance abuse was the most significant cause of pre-AIDS death among women in Providence. Further research will enable us to better understand and intervene in the complex problem of substance abuse. As HIV therapy continues to improve, the importance of treatment and prevention of substance abuse among HIV-infected patients will only increase.

(The full article appeared in the May 28 issue of *AIDS*.)

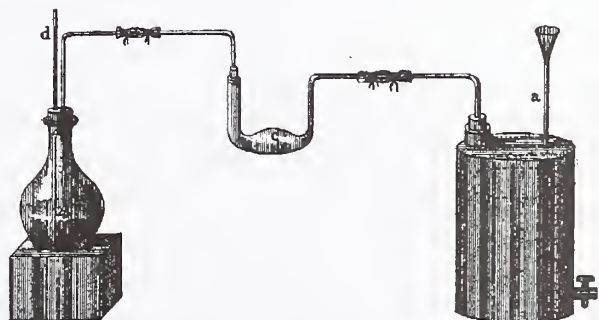
Thyrotoxicosis Presenting with Respiratory Failure

Moses Aboagye-Kumi, MD, Gary S. Richardson, MD, and Allan Erickson, MD
Veterans Administration Medical Center

A 49 year-old man with no significant medical history presented to the Providence Veterans Administration Medical Center with worsening shortness of breath, palpitations, diaphoresis, and substernal chest pain. He had been seen twice in the emergency room over the preceding month for rash and nervousness for which he was prescribed prednisone and diazepam. He had lost 25 pounds over six months, had excessive sweating, restlessness and insomnia. He took no other medications. He had smoked in the past but denied any intravenous drug use. He worked as a nurse's aide. Physical examination revealed an anxious man in severe respiratory distress. He was afebrile, tachycardic at 150 beats/minute; his blood pressure was 193/100 mmHg. His mucous membranes were dry; he had a diffusely enlarged thyroid gland without nodules. Lung examination revealed diffuse expiratory wheezes. Laboratory studies showed a white blood cell count of 17,000/uL, hematocrit was 42%. CPK was 480U/L. Chest xray was normal; EKG showed only sinus tachycardia. His ABGs on 35% oxygen included pH 7.34, PCO₂ 54, PO₂ 73 torr. He was admitted to the Intensive Care Unit and an acute MI and pulmonary embolus were excluded. His ventilatory status deteriorated, and he was intubated and mechanically ventilated. He was treated with antibiotics, steroids, propylthiouracil, iodine, diltiazem, and metoprolol initially with an admitting diagnosis of hyperthyroidism and asthmatic

bronchitis with respiratory failure. Thyroid function tests revealed thyroid stimulating hormone <0.03uU/mL, and anti-thyroid antibodies were negative. He improved on the above therapy and was extubated 48 hours after admission and discharged 5 days later. His T₄ was down to 14, his respiratory status was dramatically improved, as was his tachycardia. PCO₂ on discharge was normal. PFTs one month later showed an FEV₁ of 2.0L, i.e., only a mild obstructive defect.

Although he presumably had undiagnosed and untreated asthma or chronic bronchitis before his presentation, his thyroid disease appears to have been responsible for his respiratory failure perhaps on the basis of muscle fatigue. Although thyrotoxicosis is known to worsen asthma, respiratory failure is distinctively uncommon. This represents an unusual and perhaps unique complication of thyrotoxicosis.



ERCP and Clinical Decisions in Alcoholic Pancreatitis

*Chad W. Brecher, BS, Philip Vaidyan, MD, and Edward Feller, MD
The Miriam Hospital*

Management strategy for pain relief in alcoholic pancreatitis commonly depends on knowledge of pancreatic duct anatomy. Endoscopic retrograde cholangiopancreatography (ERCP) is useful to assess feasibility and type of surgical or endoscopic therapy. We report our experience to alert clinicians to the spectrum of findings and utility of endoscopic pancreatography in management of pain in alcoholic pancreatitis. Methods: Ninety-four patients with alcohol abuse and chronic pancreatitis were studied. All had ERCP specifically to aid clinical decisions for pain control. Results: Age range was 23-64 years. Pancreatography revealed an ectatic, dilated main duct [23 patients], small duct with changes of chronic pan-

creatitis [45], normal duct [9], ductal obstruction or stricture [11], unsuccessful study [6]. Unexpected pathology in 17 cases included gastric ulcer [2], common bile duct stone [3], gallstone [3], pseudocyst [3], pancreas divisum [2], pancreatic carcinoma [2], ampulla stenosis [2]. Conclusion: ERCP is important in decision-making in alcoholic pancreatitis to stratify patients with chronic pain into groups with a dilated cut amenable to surgical drainage, and those with a small or normal sized cut requiring resection or possible endoscopic therapy. Indeterminate or misleading findings occur. Alternative relevant pathology may be found in a substantial number of cases.

A Comparison of Accupril and Losartan in the Progression of Chronic Renal Disease in Rats

*Afshin Parsa, MD, Krupa Rajur, MD, Evelyn Tolbert, Y Liu, PhD, and Lance D. Dworkin, MD
Rhode Island and Miriam Hospitals*

Angiotensin converting enzyme inhibitors (ACEI) have been shown to stabilize renal function in certain chronic renal disease. However, since ACEI decrease occupancy of all classes of AII receptors and have important AII-independent effects, such as increasing bradykinin levels, the exact mechanisms by which ACEI decrease renal injury are uncertain. The availability of AII receptor antagonists (AIIA) allows a more precise examination of the relationship between AII and renal injury. In fact, because AIIA selectively blocks the AII type 1 receptor (and not the AII type 2 receptor), they might be less effective than ACEI in preventing kidney damage. In this study, in order to compare the effects of an ACEI and an AIIA on kidney structure, function, and degree of apoptosis in chronic renal

disease, rats that underwent 5/6 ablation of renal mass were either untreated, given the ACEI Accupril, or the AIIA Losartan. After 6 weeks, awake systolic blood pressure, proteinuria and glomerular filtration rates were measured. The kidneys were then perfusion fixed and kidney weight/body weight ratios and number of apoptotic cells per glomerulus were measured.

Our results demonstrated that ACEI and AIIA were similarly effective in reducing blood pressure, proteinuria, glomerular apoptosis, and preserving GFR in remnant kidney rats. Only Accupril significantly inhibited compensatory kidney growth. These findings are consistent with an important role for AIIA in stabilizing progressive kidney damage, primarily via occupancy of AII type 1 receptors.

Case Report: Type II Hyperlipoproteinemia with Associated Hypergammaglobulinemia Refractory to Standard Lipid Lowering Therapy

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Patient 1 is a 72 year-old white male with a long clinical history of well-controlled hypercholesterolemia/hypertriglyceridemia, who was free from clinical arteriosclerotic vascular disease. At the index examination, he was found to have tuberous xanthomas on the dorsal surface of his elbow, and Type III hyperlipoproteinemia based on lipoprotein ultracentrifugation (VLDL/TG=0.49). Pre-

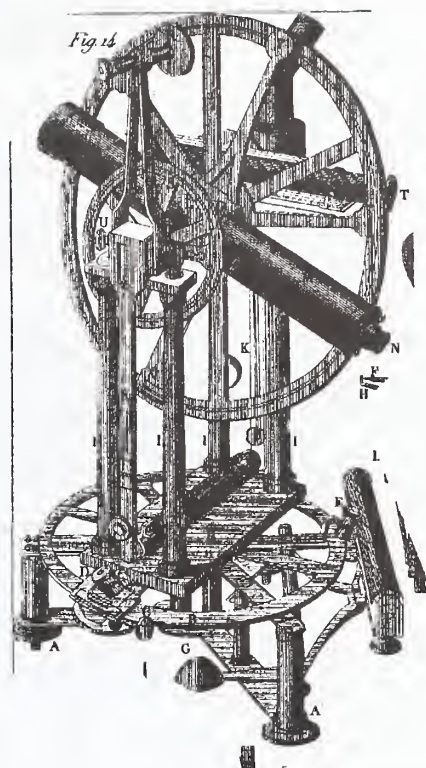
viously, the patient had normal cholesterol and triglyceride levels on an HMG-CoA reductase inhibitor nearly for 2-3 years. Within 6 months of presentation, he became refractory to simvastatin and atorvastatin. Subsequently, he was also found to be unresponsive to the treatment of choice, gemfibrozil. Immunoelectrophoresis studies identified a monoclonal IgA gammopathy in the patient.

Patient 2 is a 65 year-old morbidly obese female ex-smoker, with Type II diabetes, hypertension, cholelithiasis, and early onset cardiovascular disease. She was free of planar or tuberous xanthomas, but lipoprotein ultracentrifugation revealed a VLDL/TG=0.38, consistent with Type III hyperlipidemia. The patient was started on gemfibrozil 600 mg BID, which normalized her lipid/lipoprotein profile within 4 weeks.

Kinetic studies suggest that hypercholesterolemia associated with gammopathy is caused by the formation of immunoglobulin-lipoprotein complexes which block apoprotein sequences at VLDL, IDL and LDL recognition sites for the hepatic and

peripheral cell-surface receptors. This causes a decreased catabolism of these remnants. Type III hyperlipoproteinemia has a genetic and environmental component to its phenotypic expression. Apo E genotyping is being explored to differentiate the different isoforms to further identify the homozygosity/heterozygosity in these 2 patients.

There have been only a few reports in the literature of Type III hyperlipoproteinemia associated with gammopathies. We will compare and contrast the clinical manifestations, genetics, and responsiveness to standard pharmacologic treatment in these typical and atypical presentations of Type III hyperlipoproteinemia.



A Case of Moyamoya Disease

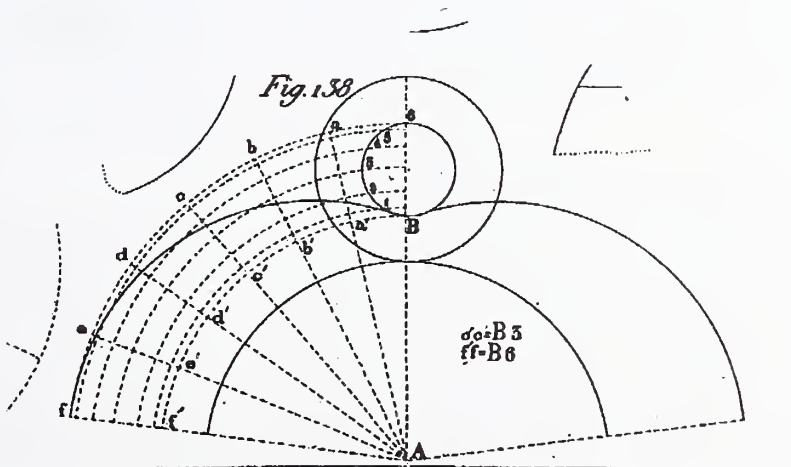
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Moyamoya disease is a rare chronic cerebrovascular disorder, characterized by progressive narrowing of the intracranial internal carotid arteries and main branches with an abnormal network of fine collateral vessels at the base of the brain. The Japanese word moyamoya describes the "hazy puff of smoke" appearance of the abnormal capillary vessels at the base of the skull. The typical presentation is ischemic strokes in children and cerebral hemorrhages in adults. Herein we describe a case of moyamoya presenting as recurrent transient ischemic attacks and strokes.

The patient, a 42 year-old right-handed white woman, presented with acute-onset of left arm and left leg weakness for a period of 4 hours following intercourse. There was no associated headache, vertigo, nausea or vomiting. The patient did not lose consciousness or report any seizure activity. She had reported similar episodes, usually lasting from 2 to 10 minutes, following intercourse over the past 4 months. Physical examination, approximately 6 hours after onset of symptoms, was significant only for mild left hand clumsiness with fine motor movement abnormalities. Past medical history was significant for a stroke at age 28, which presented with left-sided hemiparesis, which resolved completely. That event was attributed to oral contraceptive medication. There was no history of other cerebrovascular risk factors. Family history was non-contributory. CT scan of the head revealed a tiny hemorrhage seen in the right basal ganglia and evidence of old infarcts in right frontal lobe and right caudate nucleus head. Taking into account the history of recurrent ischemic and hemorrhagic stroke in a young woman, the differential diagnoses included vasculitis (both isolated CNS and systemic), ce-

rebral arterio-venous malformation, infective endocarditis, recurrent cardioembolic events, fibromuscular dysplasia and moyamoya disease. Amyloid angiopathy was excluded on the basis of the patient's age. Cranial MRI/MRA was consistent with bilateral moyamoya disease affecting the anterior circulation. Cerebral angiography confirmed the diagnosis.

Moyamoya remains a puzzling disease, with no identifiable etiology. There are two peaks of incidence, one in the first decade of life and another in the third or fourth decade. While not diagnostic, there are characteristic findings on CT and MR imaging. Diagnosis is made by procedures: 1) superficial temporal artery - middle cerebral artery anastomosis; 2) encephaloduro-arteriosynangiosis; 3) encephalomyosynangiosis. Our patient underwent bilateral encephalomyosynangiosis in two stages and is doing well.



Prevalence of *Helicobacter pylori* in Physicians and Medical Students: A Serology-Based Survey

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Helicobacter pylori has been identified as a cause of chronic gastritis, a key etiologic factor in peptic ulcer disease and possibly gastric malignancies. *H. pylori* is a gram-negative, spiral, flagellate bacillus which is non-invasive and lives in the mucus that overlies the gastric mucosa. However, little is known of the actual mode of transmission for *H. pylori*. Because the bacteria can be cultured from feces, fecal-oral or oral-oral modes of transmission have been theorized. Thus, the prevalence of *H. pylori* infection may be higher in health care workers, especially those involved with endoscopic procedures. Previous studies have concluded that physicians are at increased risk for *H. pylori* infection. This study was designed to examine *H. pylori* infection rates among physicians at various levels of their training and careers, specifically as pre-clinical medical students, clinical medical students, house officer/fellows, and attending physicians.

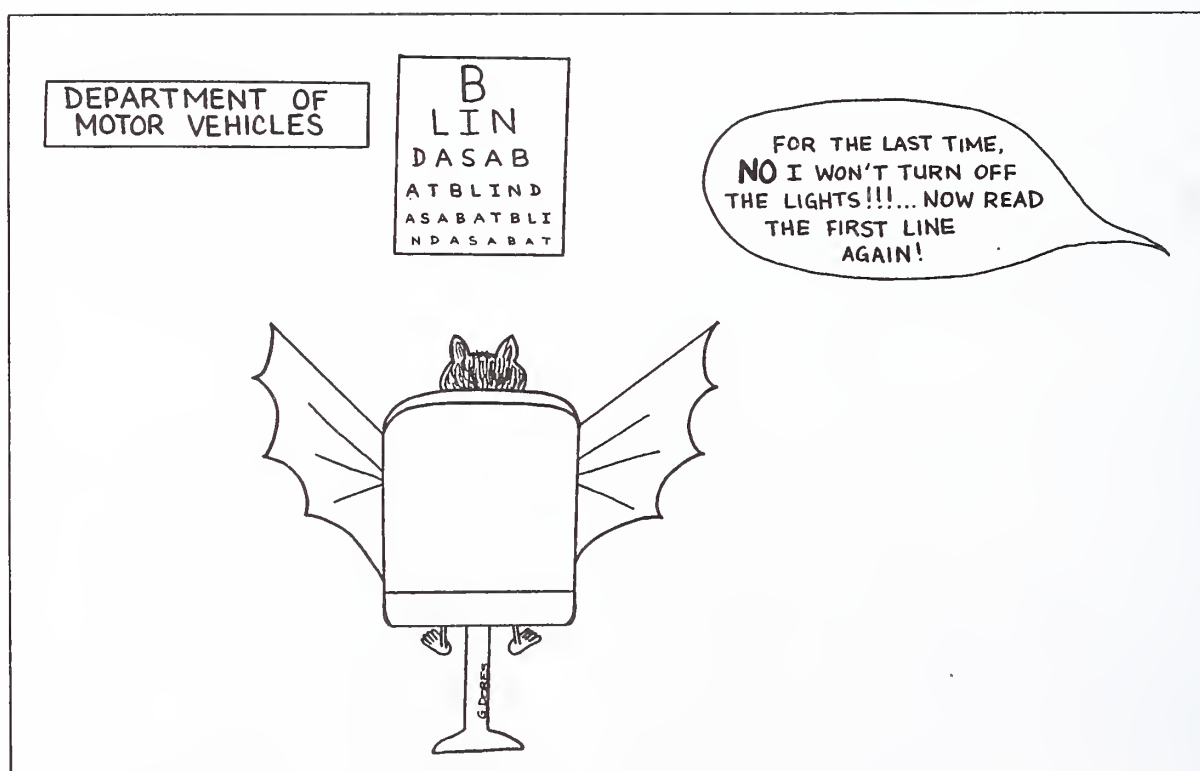
Venous blood was obtained from all study participants to determine prior exposure using IgG antibodies against *H. pylori* by enzyme linked immunoassay. An extensive questionnaire designed to assess possible risk factors for *H. pylori* infection was completed by all study participants. A control sample of the general population will be obtained from volunteers at the local blood bank.

Preliminary Results: Thus far, 80 medical students have completed the questionnaire and provided venous blood samples. Of these, 3.7% are positive for antibodies to *H. pylori*. Subset analysis of the medical students reveals 2.56% positivity in the pre-clinical students and 4.88% positivity in the clinical students. Forty-five house officers and fellows have to date participated in the study: 28.8% had positive serology for *H. pylori*. Although a significant portion of the data remains to be collected, this study indicates that the serological evidence of *H. pylori* infection increases dramatically in physicians with increased clinical exposure.

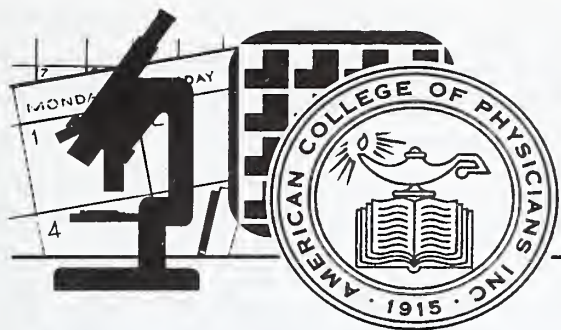
Corneal Arcus Senilis and Dyslipidemia

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This abstract was the Creative Clinician: Case of the Month, *Medicine & Health/Rhode Island*, May 1998.



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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Post Transfusion Non-Cardiogenic Pulmonary Edema in a Patient with Chemotherapy-Related Hemolytic Uremic Syndrome

Neil J. Kluger, MD, Frank J. Cummings, MD, Neal E. Ready, MD, PhD,
Joseph D. Sweeney, MD and Alan B. Weitberg, MD

Non-cardiogenic pulmonary edema is an infrequent complication of blood product transfusion. We present a patient who experienced this complication coincident with chemotherapy-related hemolytic uremic syndrome. In this setting, non-cardiogenic pulmonary edema appears to have a different incidence and etiology than the transfusion-associated non-cardiogenic pulmonary edema seen in the general population.

CASE REPORT

This 42 year old woman with metastatic breast cancer presented to the Roger Williams Medical Center emergency department in July, 1996, with a one week history of dyspnea, fever, and chills that had worsened over the previous two days. In September, 1987, she had undergone a left modified radical mastectomy for an infiltrating ductal carcinoma, stage 1 (defined as a tumor 2 cm or less in its greatest dimension with no lymph node involvement or metastatic spread). Estrogen and progesterone receptors were negative. Adjuvant treatment was not given. In September, 1992, biopsy of an enlarged left cervical lymph node showed poorly differentiated adenocarcinoma consistent with a breast primary. Over the next four years she was treated with several chemotherapeutic regimens, as well as radiation therapy, each with ultimate disease progression. She had recently failed a course of mitomycin C, (last dose received 11 weeks prior to presentation), with an abdominal CT scan three and a half weeks later

showing a slight increase in the size of a liver metastasis. She was then given palliative radiation and cisplatin for left neck pain.

The patient had no history of congestive heart failure or coronary artery disease. She had received a total cumulative dose of adriamycin of 225 mg/m².

PHYSICAL EXAMINATION

The patient was found to be mildly short of breath with the following vital signs:

Temperature: 99.8, RR 24/minute, Pulse 112/minute, BP 150/100. She did not have a pulsus paradoxus.

Head, eyes, ears, nose and throat were unremarkable. There was no jugular venous distention. Lung exam revealed decreased breath sounds at the left base and rales at the right base. Cardiac exam revealed a regular rate and rhythm. Neither an S3 nor a pericardial friction rub was appreciated. Abdominal exam revealed an enlarged liver. There was no splenomegaly. The extremities revealed no clubbing, cyanosis, or edema. Neurological exam showed no deficits.

Chest X-ray showed cardiomegaly, a small left pleural effusion, and a right lower lobe infiltrate.

EKG showed sinus tachycardia.

Echocardiogram showed a mild pericardial effusion with good left ventricular function.

Abbreviations Used:

BUN	blood urea nitrogen
C-HUS	chemotherapy-related hemolytic uremic syndrome
LFTs	liver function tests
PRBC	packed red blood cell transfusion
TRALI	transfusion related acute lung injury

LAB VALUES

Pulse oximetry on room air showed an oxygen saturation of 99%. Hemoglobin was 8.6 gm%, the hematocrit was 24.8%, the platelet count was 9,000/ul and the white blood cell count was 6,400/ul with 87% segmented neutrophils, 3% band forms, and 10% lymphocytes. Blood urea nitrogen (BUN) was 60mg%, the creatinine was 2.1mg%, the sodium was 139meq/l, the potassium was 4.3meq/l, the chloride was 109meq/l, and the bicarbonate was 22meq/l.

HOSPITAL COURSE

The patient, felt to have a pneumonia, was begun on IV antibiotics. She was also thought to be dehydrated and was started on IV fluids at a rate of 100 cc/hour.

For her thrombocytopenia she was transfused 8 units of platelets, which she appeared to tolerate well. A packed red blood cell transfusion (PRBC) was begun and after receiving approximately 200 ccs of the first unit (and a total of 800 ccs of IV fluid including the platelets and PRBCs), she devel-

oped pulmonary edema that did not respond to a lasix-induced diuresis of 400 ccs. She had to be intubated and placed on mechanical ventilatory support. A repeat echocardiogram was essentially unchanged.

Peripheral blood smear showed 4-5 schistocytes per high power field. A screen for disseminated intravascular coagulation was unremarkable, the lactate dehydrogenase was 4.5 times the upper limit of normal with normal to slightly elevated liver function tests (LFTs), and a diagnosis of chemotherapy-related hemolytic uremic syndrome (C-HUS) was made.

Because non-cardiogenic pulmonary edema is associated with blood product transfusion in patients with C-HUS, we raised our threshold for PRBC and platelet transfusion. Over the next three and a half weeks our patient required 14 units of PRBCs, only one of which resulted in respiratory distress. No platelets were given. On discharge the patient's pulmonary infiltrates were resolving and she was no longer oxygen dependent.

POST TRANSFUSION NON-CARDIOGENIC PULMONARY EDEMA IN CHEMOTHERAPY-RELATED HEMOLYTIC UREMIC SYNDROME (C-HUS)

In a review by Murgu of 135 cases of chemotherapy-related HUS, post-transfusion non-cardiogenic pulmonary edema is described as follows: "severe dyspnea and hypoxemia may occur, particularly following blood transfusion; this may result from the administration of as little as 150 mL of packed red cells. Associated findings usually include the presence of rales on physical examination and bilateral interstitial infiltrates on X-ray examination. The nature of the pulmonary insufficiency in these patients is not clear and often cannot be attributed to congestive heart failure. This non-cardiogenic pulmonary edema is considered a characteristic of chemotherapy-related HUS."¹ Mitomycin C is thought to be the initiating agent in most cases of chemotherapy-related HUS as it was in 128 of the above cases. However, a small number of case reports suggest that bleomycin and

cisplatin can cause this syndrome.^{1,2}

From a 1989 analysis of 85 patients with chemotherapy-related HUS, 84 of whom received mitomycin C, it was concluded that aggressive non-transfusion is the appropriate approach for these patients and that blood product transfusion should be reserved for patients with life threatening bleeding or markedly symptomatic anemia.³

There is little information concerning the mechanism of post transfusion non-cardiogenic pulmonary edema in patients with chemotherapy-related HUS. One author speculates that "intravascular coagulation may be triggered by transfusions in these patients and play a role in the pathogenesis of the microvascular lesions."¹ Of note is that this is different from the postulated mechanism of the non-cardiogenic pulmonary edema, known as TRALI (transfusion related acute lung injury), that can be seen in the general population after transfusion. In TRALI it is thought that HLA or anti-neutrophil antibodies in the plasma of the donor blood product interacts with the WBCs of the recipient, resulting in the activation of complement (C5a in particular), which promotes neutrophil aggregation and sequestration in the microvasculature of the lung thereby causing damage to the underlying pulmonary vascular endothelium resulting in the extravasation of fluid into the lung interstitium and alveoli, causing pulmonary edema.⁴

TRALI is an infrequent event, in two institutions occurring with 1/5,000 and 1/20,000 units of blood product transfused.^{4,5} The incidence of non-cardiogenic pulmonary edema following blood product transfusion in patients with chemotherapy-related HUS is not clear from the literature. However, in our patient there appeared to have been two episodes with a total of 23 units of blood product transfused.

In summary, non-cardiogenic pulmonary edema following blood product transfusion can occur in patients with chemotherapy-related HUS, and by a mechanism that is thought to be different from that of transfusion related acute lung injury. Clinicians should be aware of this complication.

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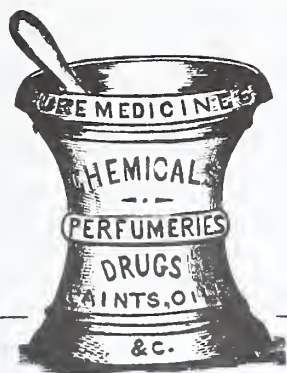
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New Anti-Parkinsonian Drugs

Hubert H. Fernandez, MD, and Joseph H. Friedman, MD

After thirty years of use, levodopa remains the mainstay of treatment for Parkinson's disease (PD). Unfortunately, it does not slow disease progression and long term complications are the rule. The development of other drugs that extend levodopa effect is, therefore, important. Three drugs have been recently approved by the Food and Drug Administration (FDA). Two are dopamine agonists, ropinirole (Requip) and pramipexole (Mirapex), bringing to 4 the total number of agonists. The other is of a new chemical class—a catechol-O-methyltransferase (COMT) inhibitor, tolcapone (Tasmar).

Dopamine agonists act directly on post-synaptic dopamine receptors. They are traditionally used as adjunctive therapy with levodopa. Pergolide, for example, is an ergot-derivative D1 and D2 agonist. Bromocriptine acts as a D2 agonist with a mild D1 and serotonin (5HT) antagonist effect. In contrast, the new drugs ropinirole and pramipexole, are non-ergoline, thereby reducing the small risk of pulmonary and retroperitoneal fibrosis, erythromelalgia, burning dysesthesias and livedo reticularis. Both drugs specifically bind to the D2 class receptors, theoretically reducing side-effects from activation of other receptors.^{1,2} Likewise, dopamine agonists theoretically decrease dopamine synthesis, thereby reducing a potential source of free radicals, implying possible neuroprotection.³

Tolcapone inhibits the breakdown of L-dopa in the blood, by blocking the degradative enzyme catechol-O-methyltransferase (COMT).⁴ It thus provides a more stable plasma level of L-dopa.

ROPINIROLE (REQUIP)

Ropinirole is a non-ergoline, highly selective D2 receptor family agonist with little or no affinity to D1, 5HT, muscarinic, or adrenergic receptors.¹ It has a half-life of approximately 6 hours and has a good oral absorption. The starting dose is 0.25 mg TID, gradually increased to an initial target of 1.5 mg TID. The maximum approved dose is 8 mg TID. Unlike older dopamine agonists, it has been approved for early monotherapy and as an adjunct to levodopa for advanced PD. In a comparison of ropinirole to placebo as

monotherapy in early disease, motor function improved by 24% at six months in ropinirole-

treated patients compared to a 3% worsening in placebo-treated patients ($p < .001$).⁵ As an add-on therapy in patients with clinical fluctuations in response to levodopa, ropinirole-treated patients had at least a 20% reduction in levodopa dose, and a 20% reduction in "off" time compared to 11% in the placebo group (odds ratio=4.4; 95% confidence interval).⁶ A 3-year study comparing bromocriptine and ropinirole is underway. The 6-month (interim) report of this double-blind study suggests that ropinirole may be more effective than bromocriptine in early PD.⁷

Despite its D2 selectivity, side-effects did not differ from bromocriptine. Most frequently reported were nausea in 56% (21% in placebo), followed by dizziness, somnolence, and infrequently, hallucinations and confusion^{5,6} (Table 1).

Abbreviations Used:

COMT	catechol-O-methyltransferase
FDA	Food and Drug Administration
PD	Parkinson's disease
3-MT	3-methoxytyramine
3-OMD	3-O-methyldopa

Table 1: Summary

	Ropinirole	Pramipexole	Tolcapone
Mechanism of action	Non-ergot D2-receptor family agonist	Non-ergot D2-receptor family agonist	Reversible peripheral and central COMT inhibitor
Dosage	0.25 mg TID titrate to 1.5 mg TID; max: 8mg TID	0.125mg TID titrate, if needed, to 0.5 mg tid; max: 1.5 mg TID	100-200 mg TID
Half-life	6 hours	3 hours	2 1/2 hours
Indications	-monotherapy for early PD -adjunctive therapy with levodopa for advanced PD	-monotherapy for early PD -adjunctive therapy with levodopa for advanced PD	-adjunctive therapy with levodopa in predominantly "wearing off" phenomenon
Side-effects	Nausea, dizziness, somnolence, hallucinations, confusion	Nausea, insomnia, constipation, somnolence, visual hallucinations	Dyskinesias, diarrhea, nausea, insomnia, somnolence, anorexia, hallucinations
Availability	0.25, 0.5, 1.0, 2.0, 5.0 mg	0.125, 0.25, 1.0, 1.5 mg	50, 200, 400 mg

PRAMIPEXOLE (MIRAPEX)

Pramipexole is a non-ergot, full agonist at the D2 receptor family (with strong specificity for D3) with little affinity for D1, 5HT, muscarinic or adrenergic receptors.² It has a half-life of 3 hours. The usual starting dose is 0.125 mg TID, titrated, if needed, to 0.5 mg TID in one month. The maximum recommended dose is 1.5 mg TID. Pramipexole is also effective in both denovo and advanced PD patients. In a double-blind study using pramipexole for monotherapy (no levodopa), pramipexole significantly improved activities of daily living (ADL) and motor function at week 24 as compared to baseline ($p < 0.0001$).⁸ For advanced PD with clinical fluctuations, pramipexole improved ADL 21%, motor function 25% and reduced "off" time period by 31% as compared to placebo.⁹ In a comparison of pramipexole to bromocriptine in advanced PD, there was only a trend which favored pramipexole over bromocriptine. Pramipexole patients, however, experienced a significant reduction in "off" hours and a more rapid and sustained "on" response compared to bromocriptine.¹⁰ Decreased anxiety, enhanced attention span, and decreased apathy were observed, as well, by investigators in the pramipexole trials.⁹

Side effects were similar to those reported with other dopamine agonists, which include nausea, insomnia, constipation, somnolence and visual hallucinations.^{8,9} The cost between different agonists seems comparable.

TOLCAPONE (TASMAR)

Tolcapone is a potent, reversible, peripheral, and to a lesser extent, central COMT inhibitor. It prevents levodopa methylation to 3-O-methyldopa (3-OMD) in the periphery, increasing the fraction of drug crossing the blood-brain-barrier for conversion to dopamine. Similarly, tolcapone suppresses some dopamine metabolism to 3-methoxytyramine (3-MT) in the brain, increasing dopamine concentration.⁴ It has a half-life of approximately 2.5 hours and is rapidly absorbed. The usual starting dose is 100 mg TID. Tolcapone is most effective in parkinsonians with "wearing off" phenomenon. In a double-blind placebo-controlled multi-center trial, tolcapone reduced daily "off" time by 3.25 hours ($p < 0.01$), with a reduction in daily levodopa intake compared to placebo ($p < 0.01$).¹¹ It is also effective in enhancing levodopa effect in patients who are stable but require increased treatment.

The most frequent adverse effect was dyskinesia which occurred in 51% receiving 100 mg TID and 64% receiving 200 mg TID (18% in placebo). Most dyskinesias developed within the first 30 days, and responded to a 25-50% reduction in levodopa dose. Other side-effects included diarrhea (13-19%), nausea, insomnia, somnolence, anorexia, and hallucinations. The onset of diarrhea was generally delayed for 4 to 12 weeks and usually resolved.^{4,11}

CONCLUSION

All 3 new drugs appear to be effective and well-tolerated therapeutic options for different stages in PD. Ropinirole and pramipexole are FDA-approved for monotherapy while

older agonists are not. Preliminary data on both drugs suggest possible superiority to bromocriptine. Side-effect profile remains similar to earlier agonists despite their selectivity to D2 receptors. Tolcapone is used as an adjunct to levodopa. It reduces motor fluctuations and allows reduction of levodopa dosage. All these are helpful but none is a "miracle" drug.

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Mammography

In recent issues of the Journal, you have read Edward Westrick's description of Rhode Island Quality Partners (RIQP) and the science of continuous quality improvement. This column offers you an example of a quality improvement project that RIQP plans to complete this year.

In the spirit of enhancing the quality of health care for female beneficiaries, RIQP identified the utilization of mammography services as an opportunity for improvement. Evidence clearly shows that mammography saves lives. Unfortunately, it is an underutilized medical technology. The overall annual mammography rate for Rhode Island senior women for calendar year 1996 was only 25.6%. When examined by age group, the rate for women age 65-74 was 31.8%; for women age 75-84, 23.5%; and for women age 85 and above, 9.3%. There was also a significant difference in rates by ethnic group. In 1996 only 20.6% of African American beneficiaries received mammograms, compared to 25.9% of Caucasian beneficiaries. Even more disheartening, only 13.9% of all other minority beneficiaries received a mammogram.

The American Geriatrics Society recommends an annual mammogram for women up to the age of 80. The American Cancer Society recommends an annual mammogram after the age of 40. The U.S. Preventive Services Task Force has listed mammography as a category "A" recommendation in combination with an annual clinical breast exam for women age 50-69. For women age 70 with a reasonable life expectancy it suggests weighing other considerations, such as the high potential burden of suffering, before deciding whether to recommend a mammogram.

Based on these recommendations and the opportunity to improve the rates as evidenced by the 1996 Medicare data, RIQP has initiated the health care quality effort described in this article. The ideas suggested by the Mammography Steering Committee which RIQP convened in late 1997, as well as successful initiatives reported in the literature and by other PROs, were very helpful in this process. The committee includes key representatives from the state's physician, provider, managed care, health department and community service organizations.

The first phase of our effort focused on educating the female Medicare population about the importance of breast

health. RIQP designed and mailed 72,000 Valentine's Day greeting cards to these seniors as a unique approach to "absorbing" the educational sound bytes. The card's message stressed the importance of having a mammogram and explained Medicare's coverage of this benefit on an annual basis. Based on feedback from the senior community, this approach was well received.

The second phase of the RIQP effort began in May. It focuses on primary care physicians because literature reports that a physician's recommendation to have a mammogram is the single most important factor which influences a woman's decision to have one.

Partners in Obstetrics & Gynecology

John J. Coughlin, M.D., FACOG

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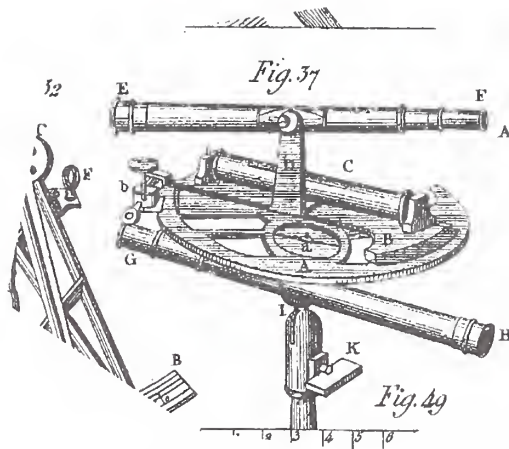
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RIQP has targeted physicians in Kent and Providence Counties for this phase of the quality improvement initiative. These counties have some of the lowest mammography rates, and are the most populated. One hundred physician offices are being asked to participate. Every office will receive a "toolkit" that includes an easy to use system for both the physician and the office manager to promote mammography. To assist in scheduling patient referrals for mammograms, the "toolkit" includes patient appointment

cards and a list of approved mammography centers. Each office will also receive a follow-up telephone call from a RIQP physician or project coordinator to respond to any questions or concerns they may have.

RIQP plans to remeasure the mammography rates using claims data from the Medicare carrier. We will compare the rates from February through October of this year with the same time period last year. We hope to see a significant increase in mammography rates statewide, as well as a more substantial increase in Providence and Kent Counties.

This is one example of the health care quality improvement efforts RIQP has initiated with the help of our collaborators on behalf of the Medicare population in Rhode Island. Plans are already in motion to reconvene the Mammography Steering Committee to help us design our 1999 mammography campaign building on this year's anticipated success. Once again, Dr. Westrick invites you to participate in

this column. Please feel free to contact him about any of our projects: phone (401) 528-3200, fax (401) 528-3210, or by E-mail ripro.ewestric@sdps.org

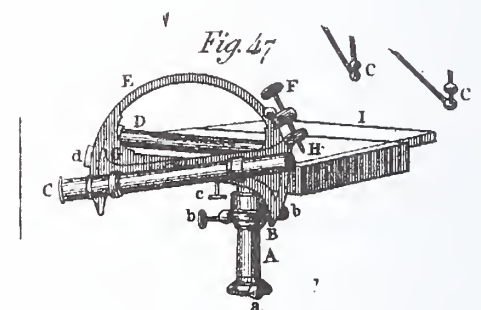
Raymond Maxim, MD, is Associate Clinical Coordinator, RIQP; Clinical Instructor, Brown University School of Medicine; and staff physician, Roger Williams Medical Center.

Marcia K. Petrillo, MA, is Executive Director at RIQP.

Debra Lafferty, MPH, is a project coordinator with RIQP.

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1. American Geriatrics Society, *Clinical Practice Guidelines: Screening for Breast Cancer in Elderly Women*. Reviewed and updated. November 1993.
2. Kimmick G, Muss HB. Breast cancer in older women. *Clinics in Geriatric Med* 1997;13:265-82
3. Nattinger AB, Panzer RJ Janus J. Improving the utilization of screening mammography in primary care practices. *Archives of Internal Med* 1989;149:2087-92.
4. *Guide to clinical preventive services: An assessment of the effectiveness of 169 interventions*. Report of The U.S. Preventive Services Task Force. Baltimore, Williams & Wilkins, 1989.



CALL FOR AUTHORS

Medicine & Health/Rhode Island will be devoting a special issue to diabetes mellitus. Primary care physicians who would like to discuss case management of patients with diabetes should contact:

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The analyses upon which this publication is based were performed under Contract Number 500-96-P519, entitled "Utilization and Quality Control Peer Review Organization for the State of Rhode Island," sponsored by the Health Care Financing Administration, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Waters, Jr., PhD

Health Care Coverage in Rhode Island, 1996

Jay S. Buechner, PhD, and Hanna Kim, PhD

The early part of this decade was characterized by declining levels of health care coverage both nationally and in Rhode Island, as unemployment rose and the provision of health insurance as a benefit of employment decreased. In response, major reform of the health care reimbursement system was proposed at the national level, but not enacted. Subsequently, health care reform experiments were encouraged at the state level, notably through Medicaid waivers allowing enrollment in managed care plans and expansion of eligible populations. Incremental national efforts have also been enacted, including the Health Insurance Portability and Accountability Act ("Kennedy-Kassebaum") and the Children's Health Insurance Program. Simultaneously, employer-driven changes in the health insurance market have fueled the rapid growth of managed care plans.¹

However, despite expanded governmental efforts, substantially improved economic conditions, and a recent respite in health care inflation, health care coverage in the population has not returned to pre-recession levels in either Rhode Island or the United States. This report provides details of the current situation in health care coverage in the state and in the trends in coverage between 1990 and 1996.

Methods

In both 1990 and 1996, the telephone-based Rhode Island Health Interview Survey obtained information on all members of participating households, including demographic, social, and economic characteristics, coverage for health care costs, and other items. In 1990, 2,588 households with 6,536 persons were included in the survey; in 1996, 2,580 households with 6,583 persons were included. For each person, the names of any government programs or private health plans providing health care coverage were obtained. For each private plan, it was further deter-

mined whether the plan was paid for entirely or mostly as a benefit of employment, either the covered individual's employment or that of another household member.

For this analysis, the health care coverage of individuals was categorized according to the following hierarchy:

Individuals with any private health plan paid for entirely or mostly by an employer were characterized as having employer-paid coverage; if their only private health plan was not employer-paid, they were characterized as having self-paid coverage. If they had no comprehensive private coverage and were covered by a government program, primarily Medicare and Medicaid (including RIte Care), they were characterized as having public coverage. All others were placed in the uninsured category.

Data from 1990 were re-analyzed according to definitions used with the 1996 survey and may differ slightly from data presented previously. Estimates of the numbers of Rhode Island residents in these categories were derived from 1990 Census population data and 1996 population estimates.

Results

In 1996, 99,000 Rhode Island residents lacked health care coverage, representing 10.0 % of the population, up from 9.1% in 1990. Among persons ages 0 to 64 years, the

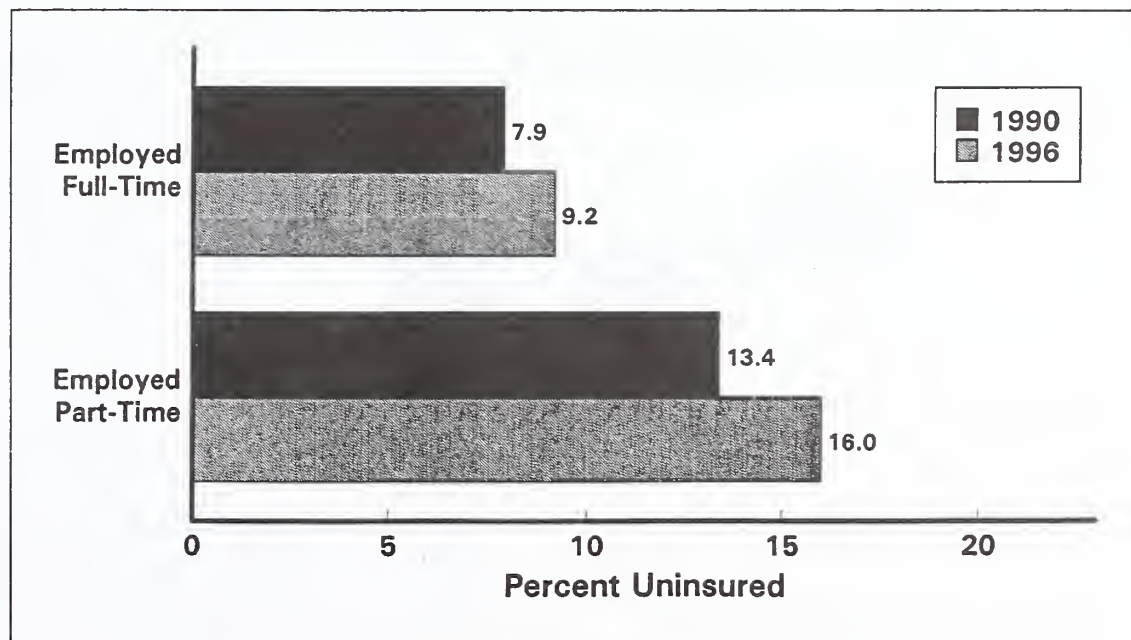


Figure 1. Percentage Uninsured, by Employment Status, Ages 18 and Older, Rhode Island, 1990 - 1996.

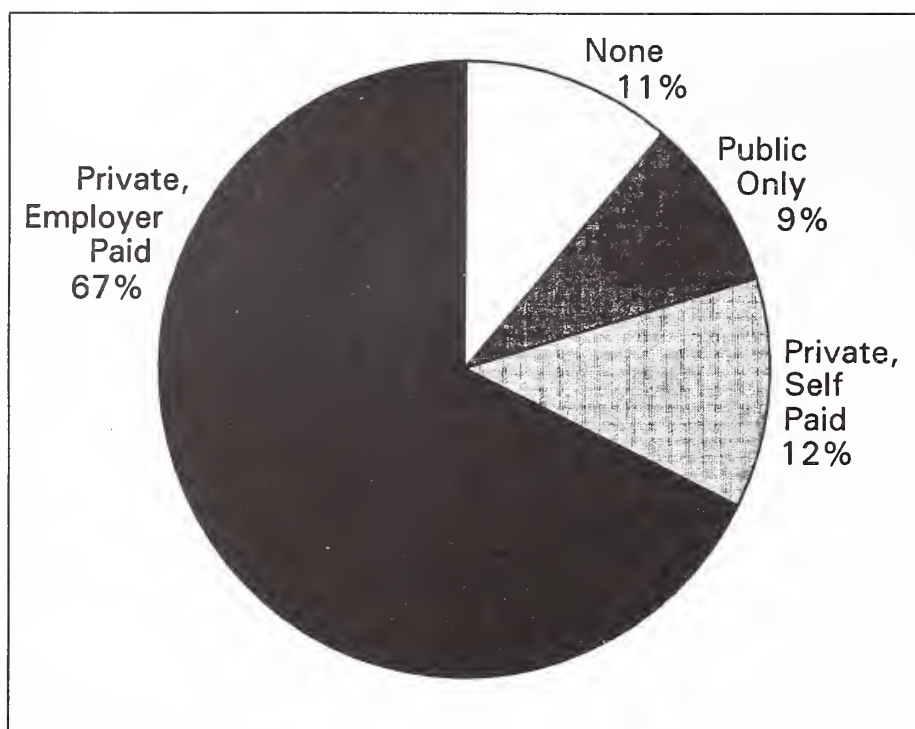


Figure 2. Source of Health Care Coverage, Ages 0-64, Rhode Island, 1996.

increase was from 10.5% to 11.1%; nationally, the increase in the percentage uninsured in this age group over a similar time span (from 1989 to 1995) was larger, from 15.9% to 17.0%.²

The large majority of employed adults (ages 18 and older) were covered by some government program or private plan, usually employer-paid private insurance, but a substantial proportion were uninsured. (Figure 1) Persons who were employed part-time were more likely to be uninsured than those working full-time in both 1990 and 1996. For both employed groups, the percentage uninsured increased between 1990 and 1996.

Among Rhode Island residents under age 65, the largest proportion were covered by employer-paid private health insurance. (Figure 2) Those covered in this way include both employees and their dependents. Substantial, but smaller, proportions of the population were covered by pri-

vate insurance plans that they paid for themselves or by government programs.

Between 1990 and 1996, there was a large decrease in the number of people covered by private health plans in Rhode Island. The majority of this decrease was among persons who paid for their own coverage, but the number with employer-paid coverage decreased also. (Figure 3) Increased enrollment in government health coverage programs partially offset this decrease, but not entirely, so that the number of uninsured persons increased by over 7,000 during the period.

Discussion

In the United States' system of health care reimbursement, there are multiple sources of coverage, each with a distinct, or nearly so, "target" population. However, this system leaves one in ten Rhode Islanders without coverage.

Efforts to expand coverage to the state's uninsured population through government programs have made advances, but have been offset by decreasing participation in private health plans.

Thus the state has experienced an increase in the number of uninsured persons during a period characterized by increasing employment and economic prosperity and unusually low inflation in health care costs. It is a concern that even under such propitious economic circumstances, there has been no apparent net progress toward the goal of universal health care coverage among the state's population.

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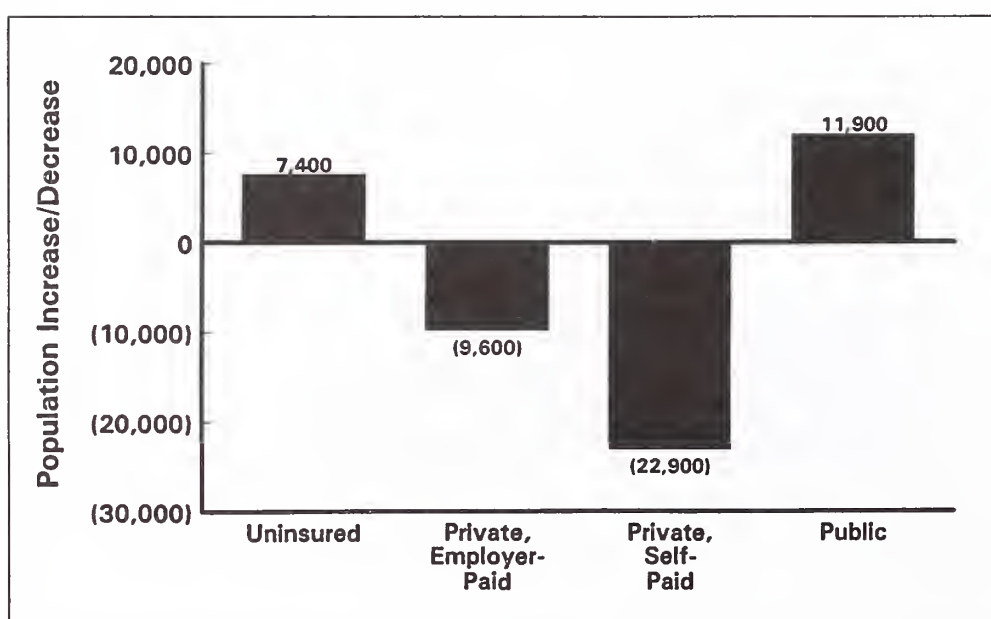
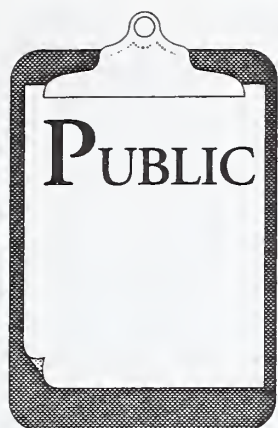


Figure 3. Change in Population by Source of Health Care Coverage, Rhode Island, 1990 - 1996.

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Proposed Prostate Cancer Screening Recommendation—Clarified

Michael Fine, MD, Barry Stein, MD, and Joann M. Lindenmayer, DVM, MPH

OBJECTIVE

In 1996 the Rhode Island Department of Health assembled an Expert Panel on Cancer Screening to advise the Department on revising the State's current cancer control plan, published in 1989.¹ After reviewing the current screening recommendations of national organizations and the most recent pertinent literature, the Panel proposed a recommendation for prostate cancer screening, inviting comments from the health care community.² On the basis of comments received, the proposed recommendation for prostate cancer screening has been clarified.

ORIGINAL RECOMMENDATION

PSA and DRE should be offered annually starting at age 50 to men with at least a 10-year life expectancy and to younger men (i.e., age 45) who are at high risk (i.e., men with a family history of prostate cancer and African-American men). Information should be provided about potential risks and benefits.

CLARIFIED RECOMMENDATION

Primary care providers should inform men ages 45 and over about the known risks and potential benefits of prostate cancer screening with the PSA and DRE, and make available annual screening with PSA and DRE to men ages 50 and over with at least a 10-year life expectancy and to men ages 45 and over with a high risk of developing prostate cancer (i.e., men with a family history of prostate cancer and African-American men) who, after considering information about the known risks and potential benefits of prostate cancer screening, request to be screened.

RATIONALE FOR THE CLARIFICATION

The comments received about the original recommendation indicated that it may be interpreted as a promotion of prostate cancer screening. It was not intended as such. Rather, the intent was primarily to inform middle age and older men about the risks and benefits of prostate cancer screening, and secondarily to make screening available to those men who request to be screened, if they fall into certain categories of risk and life expectancy, and after they have been fully informed. Accordingly, the recommenda-

tion was rewritten to clarify the proposed roles of the primary care provider and the pa-

tient, and to emphasize that the risks of prostate cancer screening are known, while the benefits are potential. As clarified, the recommendation is consistent with the majority of the current recommendations for prostate cancer screening in North America.²

Abbreviations Used:

DRE	digital rectal exams
PSA	prostate-specific antigen

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SUGGESTED TALKING POINTS FOR PATIENT COUNSELING

In accordance with the recommendation to inform men about the known risks and potential benefits of prostate cancer screening, the following talking points for patient counseling are offered as aids to physicians undertaking discussion about this issue:

- Screening for prostate cancer has become common in the United States, because it is sometimes thought to be useful in finding prostate cancer early. However, it is not clear whether or not finding prostate cancer early helps most men, for a number of reasons.
- First, it is very difficult to predict what prostate cancer will do. On the one hand, a large majority of men will develop prostate cancer before they die. Most won't die from it, or even know they have it. They have slow-growing prostate cancer. On the other hand, prostate cancer does kill many men. They have fast-growing prostate cancer. When we find prostate cancer early, in most cases we can't tell if it will be slow-growing or fast-growing.
- Second, if we decide to treat it, we are not sure if our treatment will cure it. We think that early detection and removal of fast-growing prostate cancer saves lives, but we are not sure, because we can't be sure that the prostate cancer would have been fast growing and would have killed a man had it not been removed.
- Third, we are sure, however, that some men who are treated for prostate cancer will have undesirable side effects from the treatment. Some men who are treated become unable to control urination temporarily or permanently. Some become impotent.
- Fourth, the new test used to find prostate cancer early — the PSA test — is not perfect. It sometimes indicates that a man has prostate cancer when he really doesn't have it. This is called a false positive test result. This means that unless further testing is done, a man will not know whether he really has prostate cancer or not. When this happens, a man gets worried and has to have additional testing — perhaps for nothing.
- So should we go ahead and look for prostate cancer? Experts are split on this question. On the one hand, the U.S. Preventive Services Task Force and the Centers for Disease Control and Prevention recommend against routine screening, sometimes referred to as widespread or mass screening. This means that they recommend against screening for every man. It does not mean that they recommend against screening for all men. On the other hand, the American Cancer

Society and the American Urological Association recommend annual screening for prostate cancer in African American men ages 40 and over, in men ages 40 and over with a family history of prostate cancer, and in all other men ages 50 and over, using the digital rectal examination and the PSA test.

- Many scientists are studying prostate cancer screening and treatment. In a few years, we ought to know much more about how to tell slow-growing cases from fast-growing cases, about whether or not our treatments are effective, and about who to screen for prostate cancer.
- Until then, the decision rests with a man, helped by his primary care provider. It is a personal decision, not a medical one. If you are the sort of person who would want to know if you had cancer, even if we are unsure that it needs to be treated, and that the benefits of treatment will outweigh the risks, then you may want the test. If you are the sort of person who wouldn't want to know if you had cancer, unless we could be sure it needs to be treated, and that the benefits of treatment outweigh the risks, then you may not want the test.

COMMENTS?

We invite your comments on the proposed clarification and talking points. Please send them in writing to the column editor, Dr. John Fulton, either by e-mail (FULT100w@aol.com), fax (401-861-5751), or mail (Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097).

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Judicial Diagnosis

Managed Care Plan Liability Legislation

Michele B. Lederberg, JD, MPH

A NOT IMPLAUSIBLE SCENARIO:

Managed care plan X denies coverage for a special treatment for Patient Y. Patient Y, who cannot pay for the benefit, suffers an "adverse health outcome." Can Patient Y sue Plan X for malpractice?

Federal and state legislators are debating the question.

MANAGED CARE LIABILITY: THE STATUS QUO

Currently the enrollee of a managed care plan has few options. In several cases when an enrollee attempted to sue the plan, courts found the plan not liable for malpractice because the plan itself does not engage in the provision of health care. Even when courts have found that a health plan can be liable for malpractice, many courts have held that the Employee Retirement Income Security Act of 1974 (ERISA) preempts action. In such cases, the only remedy available to the enrollee is under ERISA, but ERISA permits an aggrieved enrollee limited causes of action. The cause of action under ERISA closest to a malpractice claim is for wrongful denial of benefits. Under a "wrongful denial of benefits" claim, an enrollee can recover only the cost of benefits wrongfully denied, where in a malpractice claim a plaintiff can recover both compensatory and punitive damages.

PROPOSED MANAGED CARE LIABILITY LEGISLATION

Rhode Island state legislators recently introduced two bills that would make managed care plans subject to liability for decisions in which the plan denies coverage for a treatment or service and a subscriber suffers an adverse health outcome. In essence, these bills would allow managed care enrollees to sue their plans for malpractice. They are premised on the notion that plans should be liable for harm suffered by an enrollee who was unable to receive treatment because the plan refused to pay for it.

The bills allow a health plan certain limited defenses. In particular, they permit a plan to assert that neither the plan nor its employees influenced or participated in the health care treatment decision. Plans can also assert that they did not deny or delay payment for any treatment prescribed or recommended by a provider. Pragmatically, these defenses are limited, since the bills define "health care treatment" to include a decision which affects the quality of

diagnosis, care or treatment - in short, in virtually all circumstances a health plan would be involved in a health care treatment decision.

The federal government is also considering managed care liability legislation - although federal bills include managed care liability among a range of "patient protection" provisions, including confidentiality of patient health care information, access and coverage for use of emergency services, gag clauses, disclosure of provider financial incentives,

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and establishment of grievance and appeal procedures. Because the federal legislation addresses such a wide range of patient protection issues, a possibility exists that even if Congress passes federal patient protection legislation this session, by the time the legislation is enacted, the managed care liability portion of a bill may have been eliminated.

The Republican-sponsored "Patient Access to Responsible Care Act" (PARCA) would permit patients to hold health plan decision-makers responsible for injuries suffered as a direct result of those people's decisions. PARCA would amend ERISA: ERISA would no longer preclude any state law cause of action to recover damages for personal injury or wrongful death against any health plan that provides health benefits coverage for any enrollee in a group health benefit plan. Thus, an enrollee could sue his/her plan in state court for malpractice regardless of whether the enrollee's health benefits are underwritten by the health plan or merely administered by it.

If PARCA amends ERISA, and a health plan refuses to provide coverage for a particular service or treatment and an enrollee suffers an injury, the enrollee could sue the plan in state court for malpractice. And a court would not find that the only cause of action available to the enrollee is under ERISA.

Like PARCA, the Democratic-sponsored Patients' Bill of Rights Act of 1998 addresses a range of patient protection issues. This bill also exposes managed care plans to liability

by amending ERISA to provide that it shall not be construed to invalidate, impair or supersede any cause of action under State law to recover damages resulting from personal injury or for wrongful death against any person in connection with the provision of health benefits (whether underwritten or not) to a group health plan. The effect of this bill with respect to managed care plan liability is identical to that of PARCA: a managed care plan cannot assert, in a state law cause of action for malpractice, that the malpractice claim is preempted by ERISA.

At this time it is unclear whether Congress will pass patient protection legislation this session. Even it does, the strong opposition from many industry groups to the managed care liability provisions of the pending bills may weaken, or delete, those provisions.

Michele B. Lederberg, JD, MPH, is an associate at Partridge Snow & Hahn and a member of its Health Law Practice Group.

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A Directory of Clinical Trials

It is with pleasure that *Medicine & Health/Rhode Island* launches a new service to physicians: a directory of clinical trials. In Rhode Island, many researchers—hospital-based and community-based—are conducting clinical trials; but the channels of communication are not optimal. Consequently, sometimes a physician might have patients who would fit into a clinical trial, but the physician doesn't have details. We intend this Directory of Clinical Trials to serve as an information clearinghouse for ongoing trials in the state.

To launch this directory, we need your cooperation. Please inform us of the specifics of your trial:

- name of clinical trial
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- duration of study
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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events

	Reporting Period		
	January 1998	12 Months Ending with January 1998	
	Number	Number	Rates
Live Births	941	13,293	13.4*
Deaths	942	9,827	9.9*
Infant Deaths	(11)	(100)	7.5#
Neonatal deaths	(8)	(82)	6.2#
Marriages	281	8,087	8.2*
Divorces	264	3,151	3.2*
Induced Terminations	494	5,423	408.0#
Spontaneous Fetal Deaths	16	866	65.1#
Under 20 weeks gestation	(14)	(807)	60.7#
20+ weeks gestation	(2)	(59)	4.4#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death

	Reporting Period			
	July 1997	12 Months Ending with July 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	242	3,422	345.6	3,936.0**
Malignant Neoplasms	192	2,482	250.7	6,687.5
Cerebrovascular Diseases	48	657	66.3	842.5
Injuries (Accident/Suicide/Homicide)	30	339	34.2	6,253.5**
COPD	23	459	46.4	262.5**

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.



Book Review: Accidental Falls: Their Causes and Their Injuries

ACCIDENTAL FALLS: THEIR CAUSES AND THEIR INJURIES, by Alvin S. Hyde, PhD, MD. [Published by HAI, Key Biscayne FL 33149, 1996.]

Dr. Alvin S. Hyde has written a fascinating book about same-level accidental falls, i.e. falls of less than one story. He defines a fall as "an event which results in a person unintentionally coming to rest on the ground, or other lower level, and other than as a direct result of violence." These same level accidental falls are so common, ordinary and undramatic that their true incidence is unreported. In spite of this, S.P. Baker in 1992 was able to note that "accidental falls are the second leading cause of unintentional death ... the second leading cause of both spinal cord and brain injury ... the most common cause of hospital admissions for trauma ... (and) the source of 87% of all fractures involving the elderly. The total lifetime cost of fall injuries sustained in 1985 was about \$37 billion."

The author begins first with who falls, when they fall and where they are injured, discussing the physiologic mechanisms by which we maintain balance and the reflexes we use to protect ourselves when we do lose balance and fall. The ensuing chapters deal with the biomedical factors that cause falls, medication and iatrogenic causes of falls, and environmental hazards we all encounter. Special attention is given to the design of stairs, escalators, rugs and furniture, noting that over one million injuries are incurred annually from stair accidents alone.

The author demonstrates that it is possible to calculate the impact velocity of a body part in various types of falls. The types include: (1) a crumple or collapse, or a slip, trip or a topple, which the author terms a tumble [ie, crumple velocity of the head at impact = the square root of $2gh$; where g = the acceleration due to the gravitational pull of earth, [32.2 feet per second per second] and h = the height of the person falling; if one is interested in the hip that strikes the ground, use the height of the hip from the ground as h . Thus, for a 5 foot 6 inch woman who collapses, the velocity of her head will be the square root of $2 \times 32.2 \times 5.5$, which is 18.8 feet per second, or about 12.8 miles per hour. The greater trochanter of her hip at a standing height of 3 feet could expect an impact velocity of $2 \times 32.2 \times 3$, or 13.9 feet per second (about 9.5 miles per hour). [2] For slips, trips and tumbles, the velocity = square root of $3gh$. The difference in formula results

in impact velocities 22.5 % higher than that which is encountered in a crumple. The 5 foot 6 inch woman under these circumstances would strike her head with an impact velocity of 23 feet per second or about 15.7 miles per hour.

In fact the impact velocity may be greater than that, since, should the person be falling forward, the forward velocity at the moment before the trip should be added to the calculation. Thus, velocity = square root of $3gh$ + pre-fall velocity. These formulae reveal the awesome impact velocities which can be generated in simple same-level falls.

This book contains a wealth of information for both professional and non-professional readers in a well-illustrated and well-documented format.

— Betty E. Aronson, MD
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Cancer: A Personal Journey

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Notes from the Edge is a video of readings from the diary of a young doctor who died of cancer at 31 years of age, after a two and a half year battle. I am a Nurse Practitioner and a four-year survivor of cancer. Like Dr. Morgan, I kept a diary of my experiences with cancer; and I have also not read it since.

The video opens with Matthew Broderick describing Dr. Peter Morgan. Dr. Morgan was 29 years old, just finishing his residency in Cleveland, and preparing to enter a fellowship in hematology/oncology at Temple University in a few months. He was a dedicated physician, single, and came from a large close family. He found a lump in his leg and diagnosed it as a bruise. At some point, Dr. Morgan sought help for the lump and was told it was cancer and that he needed to go to Sloan-Kettering in New York for treatment. At this point, excerpts from his diary are read. On his way to New York, he stopped and bought a notebook to record his thoughts. His first entry was that he would never re-read what he had written.

As the diary excerpts are read, there is chamber music in the background and famous works of art, most of a tragic nature, displayed on screen. Occasionally family photos are shown. There were interviews with Dr. Morgan, his family, friends, and colleagues.

In one excerpt he lamented that he did not know how to tell his parents he had cancer. We don't find out from his diary how he told them. We have a hint of it in his father's interview, and nothing more. In another instance, Dr. Morgan talked about suicide, but we never know what occurred to change his mind. It seems that we are not privy to the soul searching he must have experienced, only

the decision he came to. Even in the interviews with Dr. Morgan, there were only glimmers of his emotional pain. In one scene, he was in the hospital getting chemotherapy and he found out that it was not working. The camera panned to his face, but he turned his head and the sorrow hung in the air. The next scene ignored the previous one, and the experience was disjointed. No excerpts from the diary mentioned the chemotherapy failure or the pain inherent in cancer. In fact, few excerpts gave insight into how he coped with the many disappointments and setbacks he suffered. One excerpt said that he wanted to die actively, but the phrase was not defined. The excerpts pique our curiosity, but never satisfy it.

For many cancer patients, a diary becomes a lifeline. It is the one place where thoughts and feelings can be expressed without having to explain or defend oneself. It allows for the dissipation of anger, pain and irritations. It helps feelings become focused and understood. Quite simply, it becomes your best friend and your psychiatrist. It is very personal, and not always nice.

I am sure that Dr. Morgan experienced shock, anger, fear, outrage, depression, and other emotional states before he came to accept his condition. It is unfortunate that we do not see how he came to this understanding and finally the acceptance of his death.

He was obviously an intelligent and articulate young man who died too soon. Unfortunately we are not allowed further access to his diary. Maybe someday the diary will be published, and we can understand how he dealt with the chaos that invaded his life. I don't believe this video does justice to the man who fought a courageous battle against cancer.

I am not sure for whom the video is intended. It does not seem appropriate for newly-diagnosed cancer patients, as watching a young man come to terms with his death may only instill more panic in their already fearful lives. And experienced oncology doctors and nurses know everyone comes to terms with death in their own way, none better than another. No matter who views this video, they will see a remarkable young man. Unfortunately, they will see the man, but not his soul.

— Carol A. Jacques, RN, NP

Department of Neurology
Memorial Hospital of RI



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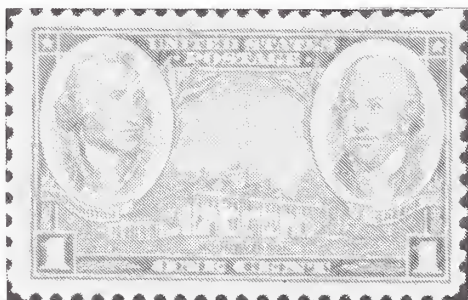
Rhode Islanders on United States Postage Stamps

The following five Rhode Islanders grace United States postage stamps.

- 1) Oliver Hazard Perry [U.S. 1890-93, Scott #218]
Born: August 23, 1785, South Kingstown, RI
Died: August 23, 1819, off Port of Spain, Trinidad
Commodore, United States Navy
Famous for message: "We have met the enemy, and they are ours."



- 2) Nathanael Greene [U.S. 1936-37, Scott #785]
Born: August 7, 1742, Warwick, RI
Died: June 19, 1786, Mulberry, Georgia
Major General, United States Army, during the Revolutionary War



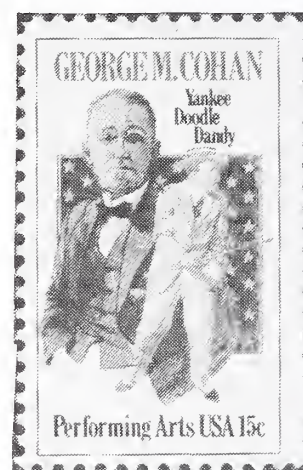
- 3) Gilbert Stuart [U.S. 1940, Scott #884]

Born: December 3, 1775, North Kingstown, RI
Died: July 9, 1828, Boston, Massachusetts
American portrait painter, especially of George Washington



- 4) Matthew Galbraith Perry [U.S. 1953, Scott #1021]

Born: April 10, 1794, South Kingstown, RI
Died: March 4, 1858, New York, New York
American Naval Officer, opened world trade with Japan



- 5) George M. Cohan [U.S. 1978, Scott #1758]

Born: July 3, 1878, Providence, RI
Died: November 5, 1942, New York, New York
Father of musical comedy, best remembered for *Yankee Doodle Dandy*

CORRESPONDENCE:

J. Tierney
111 Amherst Ave.
Pawtucket, RI 02860



NINETY YEARS AGO

[JULY, 1908]

The annual address of the new president of the Rhode Island Medical Society, Charles V. Chapin, MD, provides the lead article. Chapin discusses the many solved and unsolved problems of sanitation. Amongst the laudable sanitary successes of the last century, he lists such major accomplishments as the cleansing of cities, the providing of pure water, the removal of wastes, the scientific purification of sewage, the development of bacteriology as a major science, the discovery of the etiologic agents of many infectious diseases, the mechanisms by which certain diseases are transmitted, and the public health control of certain major diseases such as cholera, typhoid and malaria. Of

the many unsolved problems in the sphere of public health, Chapin lists [and discusses] such vexatious questions as the mechanisms by which bacteria travel from person to person, the portal by which germs enter the host body [particularly the acid-fast bacillus], the role of fomites in transmission, what diseases, if any, are carried by the common temperate-climate insects, the role of healthy carriers, and what should be done with identified carriers? There are yet other problems, he contends, including the evils of alcoholism and venereal disease. Furthermore, in society's zeal to control disease by restricting personal liberties or by destroying personal properties believed to carry infective material, one should be absolutely certain of the critical role of carriers or of fomites in the enhancement of contagion before undertaking these measures.

FIFTY YEARS AGO

[JULY, 1948]

The lead article considers the neurological aspects of poliomyelitis. Henry B. Viets, MD, discusses, first, the bulbar form of the disease with a current mortality rate in excess of 20%. He notes, though, that by means of rapid diagnosis, speedy transportation to appropriate hospitals, the use of tracheotomy, oxygen and mechanical respiration, the mortality rate has been reduced to about 5%. The author concludes that every community should have a polio commission to plan for any exigency.

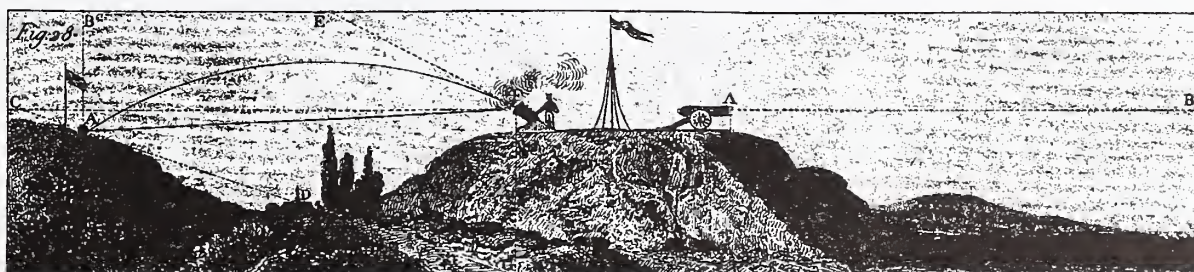
Edward Bortz, MD, president of the American Medical Association, presents a paper entitled The Challenge of Medicine in the Atomic Era. He discusses, first, the atomic elements of medical importance, particularly those isotopes which may be of great diagnostic or even therapeutic value. He then considers the new frontiers which medicine must

address in the ensuing decade. He particularly stresses those aspects of social medicine the existence of which the profession can neither deny nor delegate, in conscience, to another profession.

Vincent J. Oddo, MD, describes a new method for the treatment of hydrocele. The author has devised a new surgical procedure which preserves the endothelial cells of the tunica vaginalis with a permanent aperture allowing the outer capillary bed to absorb any excess fluid.

The elements of staff organization in a hospital setting are described in detail by Charles F. Wilkinson, Jr, MD. He discusses such issues as the division of services, the staffing according to the bed-size of the institution and the relationship among fulltime staff, attending staff and the house staff.

The Journal pays tribute to Guy William Wells, MD, who died at age 57 while serving as chief of internal medicine at both Rhode Island and Memorial Hospitals. He also served as president of the Rhode Island Medical Society.



TWENTY FIVE YEARS AGO



[JULY, 1973]



The introductory remarks for the eighth [1971] and ninth [1972] annual Maurice N. Kay pediatric symposia are presented by Mary Arnold, MD, and Leo Stern, MD, respectively.

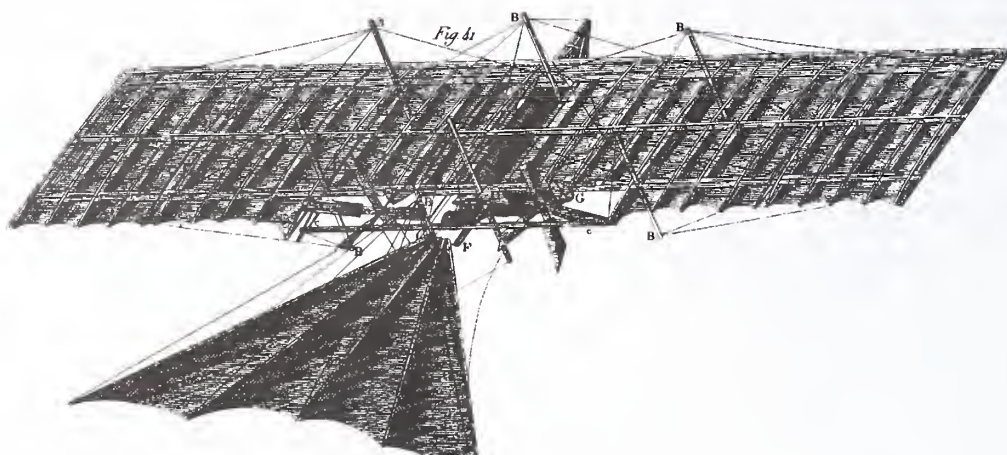
H. Boutourline Young, MD, presents a paper summarizing the environmental influences upon the time of onset of puberty in both male and female. The author distinguishes puberty [the process of physical sexual development] from adolescence [the process of emotional as well as physical development and adjustment.] His discussion touches upon methods for assessing quantitative development during puberty, the endocrinologically determined stages of

the process, body build and physical maturation, seasonal changes with puberty and the socio-economic factors which modify the time and character of the onset of the menarche.

John W. Grover, MD, discusses the many problems associated with emerging sexuality and their medical management. He emphasizes that most medical schools do not prepare their students with the skills and understanding to confront and manage such problems as teenage pregnancy and venereal disease in the young.

Drug disposition in the fetus and newborn infant are considered by Sumner J. Yaffe, MD. The author considers, specifically, the process of absorption, distribution, metabolism and excretion in both fetus and newborn.

Georges Peter, MD, describes Hemophilus influenzae disease drug therapy as well as the prospects for an effective vaccine against hemophilus meningitis.



Information for Contributors

Medicine & Health/Rhode Island welcomes submissions from members of the Rhode Island health care community. Submissions can fall into one of three categories:

CONTRIBUTIONS

Contributions should report on an issue of interest to clinicians in the state: new research, treatment options, collaborative interventions, review of controversies. The maximum length of submissions is 2500 words; the maximum number of footnotes is 15. (The Journal is not the venue for an exhaustive literature review). Tables, charts, and figures should be camera-ready. Photographs should be black and white. (Slides are not accepted.)

CREATIVE CLINICIAN

Clinicians are encouraged to submit brief (no more than 1200 words) descriptions of cases that defy textbook analysis. Photographs, charts, and figures may accompany the case; footnotes should not exceed 6.

POINT OF VIEW

This column gives readers an opportunity to share their perspective on any issue facing clinicians. The topic is broad:

it could, for example, include ethics, health care policy, and/or relationship with patients. Maximum length is 1200 words.

The format of submissions is as follows:

The title page should include name, affiliation, address, phone, fax, and email. A brief abstract should appear on a separate page. References should be numbered sequentially in the text, and listed separately at the end of the document (not the end of each page).

For Contributions and Point of View, please submit 4 hard copies of the document, with a disk (Microsoft Word or Text), to the managing editor, Joan Retsinas, PhD, 344 Taber Avenue, Providence, RI 02906.

For Creative Clinician columns, please submit 3 hard copies of the document, with a disk (Microsoft Word or Text), to Anthony Mega, MD, Miriam Hospital, Providence, RI 02906.

For additional information, please contact Joan Retsinas (phone/fax: (401) 272-0422; e-mail JRetsinas@aol.com)

BOOK REVIEWS

Medicine & Health/Rhode Island will review books authored by Rhode Island physicians. Publishers should send a copy for review to the managing editor.



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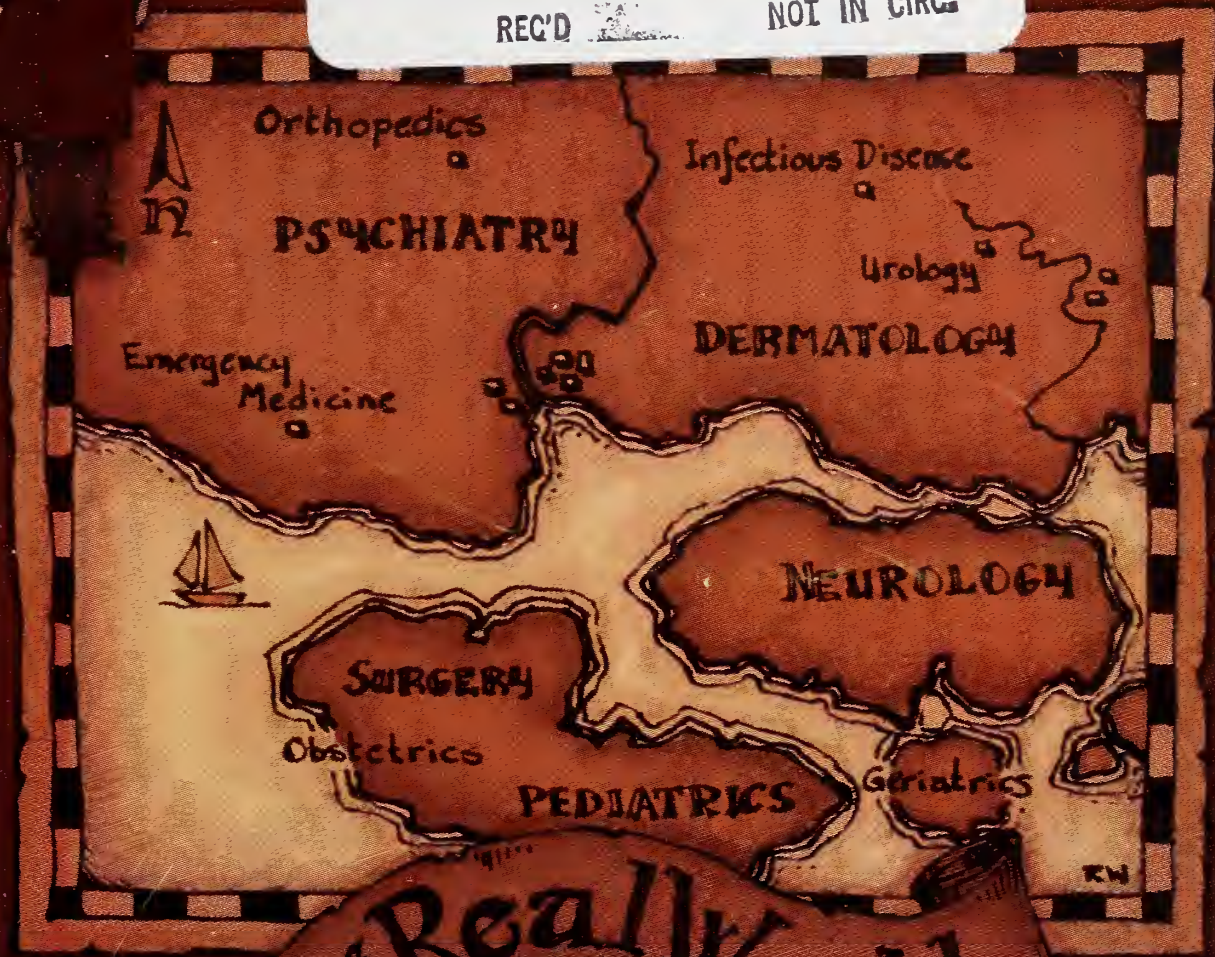
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The Rash That Kills



Rarely is the success of an action judged solely by the extent of its positive effects; unless, of course, it is accompanied by a full measure of orchestrated pizzazz. Success, like beauty, remains in the eye of the beholder. Take, for example, the bland announcement from the Centers for Disease Control and Prevention [CDC], US Public Health Service, dated April 17, 1998: "During 1997, a provisional total of 138 confirmed measles cases was reported to CDC by local and state health departments, the lowest number of measles cases ever reported in one year."

Most adults regard measles as a benign illness of early childhood, dimly recalled as a week confined to a darkened bedroom. Accordingly, the bulk of American newspapers treated this news release with the same breathless enthusiasm as a report on soy bean yield from Outer Mongolia. Yet this banal declaration distills in 31 words one of the great success stories of the 20th Century.

Measles is a highly contagious airborne viral infection of childhood. Indeed, except for a few rain forest tribes isolated from the remainder of humanity, exposure to measles - until 35 years ago - was almost as inevitable as death and taxes. Along with loss of baby teeth and innocence, most adults classified it as an obligatory price for transit into adolescence. Permanent immunity is achieved after recovery from infection or after the use of an effective vaccine.

In 1963 an effective measles vaccine was devised; and the world then changed. To appreciate the magnitude of this change, consider the impact of measles in a typical year immediately prior to the widespread application of a preventive vaccine. In 1958, for example, there were 763,000 *recorded* cases of measles in the United States. [The actual number was substantially greater since many cases customarily went unreported.] An estimated 100,000 of these cases were complicated

by pneumonia or ear infection; about 1,000 developed measles encephalitis; and 150 children died.

Back in 1905 when Providence recorded a population of 194,000, there were 531 reported cases of measles with 81 deaths during a six-month interval. Deaths from all causes during that interval had been 2,105. Measles, therefore, accounted for almost 4% of all deaths and was then the leading cause of childhood mortality.

By 1964, a year after the measles vaccine was introduced, measles morbidity in this country dropped precipitously. By 1977 a nationwide childhood immunization initiative sought to raise measles immunization levels to 90% with the hope of eventually eliminating indigenous measles. [Indigenous measles defines those cases contracted in this country but are not part of an infectivity chain originated by an index case from a foreign country.] By 1981 there were fewer than 3,000 measles cases per year in the United States and most were confined to those border states admitting large numbers of foreigners [eg, California, Florida, New York, Texas, Arizona.] By 1981, every state had passed laws specifying measles vaccination as a requirement for entrance into the public schools. Exceptions were made for those parents who objected to immunization on philosophic or religious grounds.

The number of reported cases in the U.S., last year, was 138, the overwhelming majority being foreign importations. Based upon a meticulous virologic screening of each of these cases, the Public Health Service boldly concluded "... there is no endemic circulation of measles virus in the United States." In other words, there were no cases of home-grown measles in this country and those isolated, imported cases rarely infected more than a handful of susceptible children, most often those who had previously refused immunization.

And what about the remainder of the world? In 1990 the World Health Organization reported: "Measles kills more children than any other single disease. Last year, measles killed over two million children." To appreciate the enormity of this statistic, consider that deaths in the United States *from all causes*, in the same year of 1990, was 2,148,000. Why then should measles, remembered by most Americans as an annoying but brief illness, annually kill more children worldwide than all the fatalities from cancer and heart disease in the United States?

A well-nourished 5 year old youngster will handle the measles infection with relative ease. In developing nations, however, measles infections tend to occur at a much younger, more vulnerable age. Thus, when the measles virus attacks a marginally malnourished 8 month-old it will weaken the infant's immune system to such a degree that superimposed lung, intestinal and eye infections will lead to profound weight loss, stunting of growth, corneal ulcerations [often causing blindness] and an overall mortality rate in excess of 15%. The measles virus has been compared to the AIDS virus; both effectively suppress immune response; one enduringly [AIDS] and one transiently [measles.]

The World Bank has declared that measles immunization is the most cost-effective health care measure in the developing nations of the world.

In 1796, Dr. Edward Jenner developed an effective vaccine against smallpox; and 1979, 183 years later, witnessed the last natural case of smallpox on this globe [a health worker in Somalia.] Smallpox is now declared to be extinct. Perhaps measles will soon join this singular category of human disease. As the year 2000 approaches the extinction of measles would be a fitting accomplishment to mark the onset of the new millenium.

— Stanley M. Aronson, MD

Premedical Prerequisites Revisited

Stephen R. Smith, MD, Deborah Danoff, MD, and Philip Szenas, MA

Suitable preparation for medical school has been a topic of longstanding interest, dating back to the early part of this century.¹ More recently, the Report of the Project Panel on the General Professional Education of the Physician and College Preparation for Medicine (the GPEP report), published in 1984, specifically commented on baccalaureate education.² The authors stated: "Broad and thorough baccalaureate education is an essential component of the general professional education of physicians." They also indicate that many students undertake this education with the very narrow objective of getting into medical school and that this results in premature specialization and a failure to obtain a broad rigorous education. This is reinforced by the lists of required courses and the emphasis on the science MCAT. Amongst the GPEP recommendations were broadening the preparation to include natural and social sciences and the humanities and modifying admission requirements to require only essential courses (they also suggested experimenting with no required courses).

Since the publication of the GPEP report, a number of thoughtful papers have discussed the preparation for medical school. In 1995, Stimmel and his colleagues at Mt. Sinai noted "medical schools have always attempted to admit as diversified a class as possible but are usually constrained by requiring the traditional premedical courses."³ As the authors point out, these requirements can produce extremely competitive students who focus on grades rather than on obtaining a true broad-based undergraduate education.

Despite the suggestions of GPEP and the concerns of a number of medical educators, there has been remarkably little change in course requirements since 1955: the vast majority of schools still require specific

course work in physics, biology, and chemistry; a majority still require college English; fewer than one in five schools require calculus, college mathematics, behavioral/social sciences and courses in the humanities.

Making changes to premedical course requirements is not a simple matter. First, course requirements must be viewed in the larger context of the medical school admission process. Second, most applicants apply to more than one medical school; therefore, changing course requirements at one school will have little effect on the undergraduate course selection of applicants. Finally, many of the courses that medical schools would choose to take off their "required lists" are necessary to fulfill requirements for undergraduate majors.

A review of the pedagogic principles and prerequisite requirements of the Brown University School of Medicine provides an opportunity to study the forces at play in the evolution of medical education and consideration of prerequisite requirements. Brown is somewhat unique in its preparation for its entering medical students. Two thirds of Brown's entering medical students are part of its combined baccalaureate-M.D. program—the Program in Liberal Medical Education (PLME). This allows any changes in Brown's premedical course requirements to have an immediate and direct effect. Brown, the College, has no course requirements for its undergraduates beyond the requirements for a major concentration. This permits students to benefit from fewer restrictive medical school admissions requirements and explore a broad array of undergraduate courses. The integrated nature of the PLME also affords the potential for

Abbreviations Used:

AAMC	Association of American Medical Colleges
AP	Advanced Placement
GPEP	General Professional Education of the Physician report
MCAT	Medical College Aptitude Test
MEP	Medical Education Program
MSOP	Medical Schools Objectives Project
PLME	Program in Liberal Medical Education

cooperation between the medical school and the college in the development of undergraduate courses that could focus on the applicability of the discipline to medicine.

This article reviews the changes in premedical prerequisites at Brown over the last three decades, analyzes the rationale for prerequisites, and suggests guidelines to employ when establishing or revising prerequisites.

BROWN'S PREMEDICAL REQUIREMENTS

Brown re-entered medical education in the twentieth century* in 1963 with the inauguration of the Master of Medical Science (MMS) program. Students were admitted from high school to a six-year program that encompassed the four years of college and the first two years of medical school. Ward Darley, executive director of the Association of American Medical Colleges (AAMC) at the time, exerted considerable influence on the shape of the MMS curriculum. At his urging during a visit to Brown in March 1960, the MMS was shaped to produce physician-scientists.

The result was a curriculum that was heavily weighted toward the sciences. In addition to meeting the general requirements for a bachelor's degree, the MMS students were required to complete, as undergraduates,

five courses in chemistry, four in physics, three in mathematics, six in biology, three in psychology, four upper-level courses in the humanities or social sciences, five distribution courses, one course in sociology, and achieve proficiency in a foreign language at the fourth-semester level. Students were also expected to meet the proficiency requirements in English composition before the beginning of the third semester. In addition, students were required to attend a weekly seminar in the history and philosophy of medicine. This added up to a total of 31 undergraduate courses. Summers were included, the first being utilized for remedial work, if necessary.

These onerous requirements also supposed that students entered Brown with a solid scientific foundation from high school. Most MMS students were placed in an advanced one-semester general chemistry course in their first semester, rather than the typical two-semester chemistry sequence, taking organic chemistry during their second semester of their freshman year. This was followed by the second semester of organic chemistry, then two semesters of physical chemistry.

Needless to say, students were unhappy with this curriculum. Not only was it heavy in science, but biology was not introduced until the second year. The MMS curriculum came under strong student attack at the same time that Brown's overall curriculum was being challenged by Ira Magaziner and fellow student activists. Gradually,

the curriculum was modified, as illustrated in Table 1.

The MMS program was superseded by the Medical Education Program (MEP), which added the last two clinical years of medical school and awarded students a bachelor's degree and doctor of medicine degree after seven years. While still defending the idea of the physician-scholar, the faculty clearly was viewing medicine in a different social context in 1972 than it had in 1960. The faculty resolution's charge to the planning committee for the new program stated:

The curriculum should be so arranged that it reflects our appreciation that the ultimate concern of medicine is with the well-being of the human individual in the fullest sense and with the physical and mental health of the human community. The curriculum must meet the urgent needs of the broader medical education which doctors must have if they are to prepare themselves for a humanistic approach to medicine by studies providing an understanding of, and sensitivity to the broadest aspects of human experience in its personal and social dimensions. Every effort will be made to provide extensive training and experience in the fields of community medicine, preventive medicine and the administration of health services.⁴

The curriculum committee's hope that about half of the students would opt for a new liberal arts track did not

materialize. Fewer than 20% of students selected this option. Even though the liberal arts option never became a popular choice for a large number of students, the reduction in requirements for the science track permitted students to explore widely among the university's curricular offerings while concentrating in biology. As more and more of the MEP students began to opt for a full four-year undergraduate experience before entering medical school, the medical school administration embarked on a new plan—the Program in Liberal Medical Education (PLME)—that included a radical new conception of premedical requirements.

Prior to 1983, the premedical course requirements for Brown University's medical school were quite traditional: two semesters each of calculus, inorganic chemistry, organic chemistry, physics, and biology. These changed in 1983 as a consequence of planning for the PLME. The PLME admitted students from high school to an eight-year continuum that combined liberal arts and medical education.

The planners of the PLME rejected the notion of requiring specific premedical courses, choosing instead to focus on what competencies students would need to successfully enter the medical phase of their education. This resulted in some significant changes. For example, faculty did not believe that students needed to go beyond high school calculus in terms of competency in quantitative reasoning, but did believe that students should be able to use and interpret basic statistical methods in problem solving. Students needed sufficient understanding of chemistry in order to be ready for biochemistry, which, the faculty believed, did not require two semesters of organic chemistry. Nearly everything the students needed was included in the first semester of organic chemistry. Biochemistry became a course that students were expected to take as undergraduates.

Honors-level or advanced placement high school courses in biology, chemistry, physics, and mathematics

Table 1
Changes in Premedical Course Requirements for the
Brown University Master of Medical Science Program, 1964–73

Subject	Years		
	1964-66	1968-70	1971-73
Chemistry	5	4	4
Physics	4	3	2
Mathematics	3	3	3
Biology	6	5	5
Psychology	3	2	2
Humanities or Social Sciences (upper level)	4	4	0
Sociology	1	1	1
Distribution	5	5	0
Total required undergraduate courses	31	27	17

were accepted as means by which students could demonstrate competence in those areas by scoring above a standard on the advanced placement examination or the appropriate achievement test. Most PLME students met competency requirements in calculus and biology in this manner. Among the PLME students who entered Brown in 1997, at least 87% had fulfilled calculus competency, 47% had fulfilled biology competency, 35% had completed at least one semester's equivalent of chemistry, and 5% had met the physics competency. (These percentages represents only those students whose advanced placement [A.P.] scores earned them placement out of the course. The actual percentage of students who place out is higher.)

While radical for its time in 1983, other medical schools followed Brown's lead in subsequent years, typically by reducing the requirement for organic chemistry to one semester and shifting the emphasis in quantitative reasoning from calculus to statistics. However, as discussed earlier, most medical schools have not significantly altered their premedical requirements. Data collected by the AAMC on a survey of students matriculating in medical schools in 1997 indicate that fewer Brown students report taking courses in calculus, biology, chemistry, and physics, and more report taking courses in biochemistry and statistics, as would be predicted. The same proportion of Brown students report taking courses in the humanities and social sciences as do other medical students, but Brown students are more likely to report taking those courses for their own interest rather than as a requirement (see Figures 1 and 2).

Although Brown has been successful in reducing its premedical course requirements, there are continuing pressures from the medical school faculty to add new prerequisites. For example, one committee recently expressed concern that entering medical students might have deficient knowledge in cell biology. At the same time, other faculty were expressing a view that students should acquire more knowledge and skill in areas of epide-

miology and public health prior to medical school, while still other faculty were advocating for college courses in ethics.

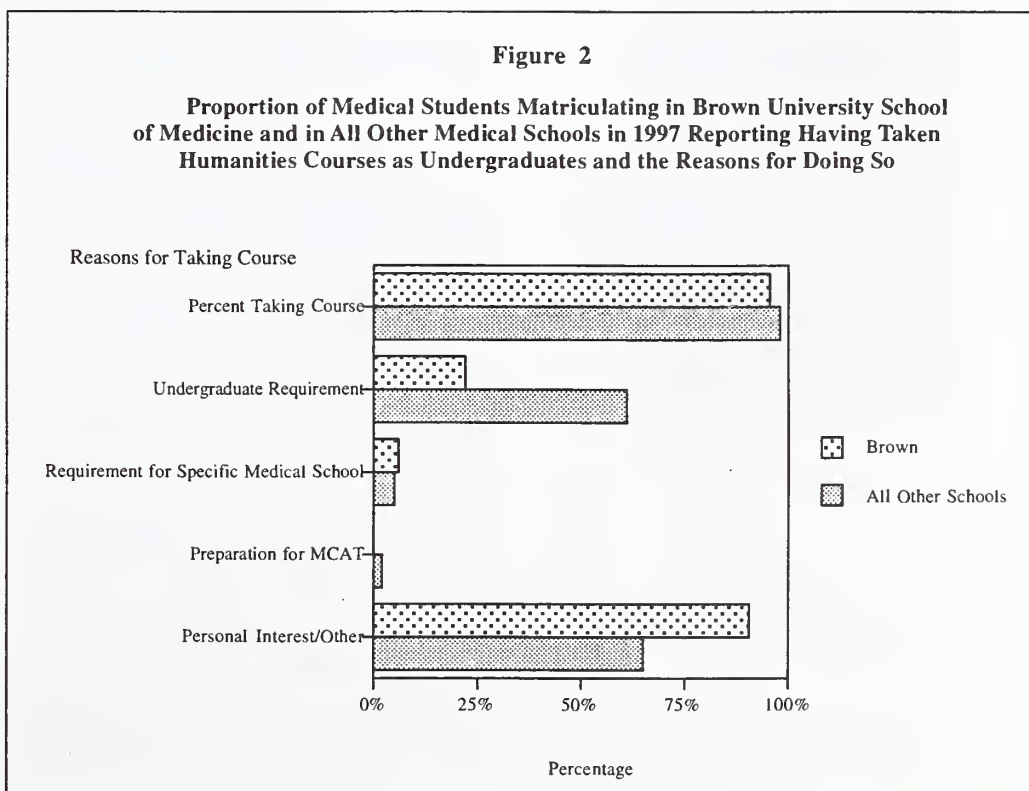
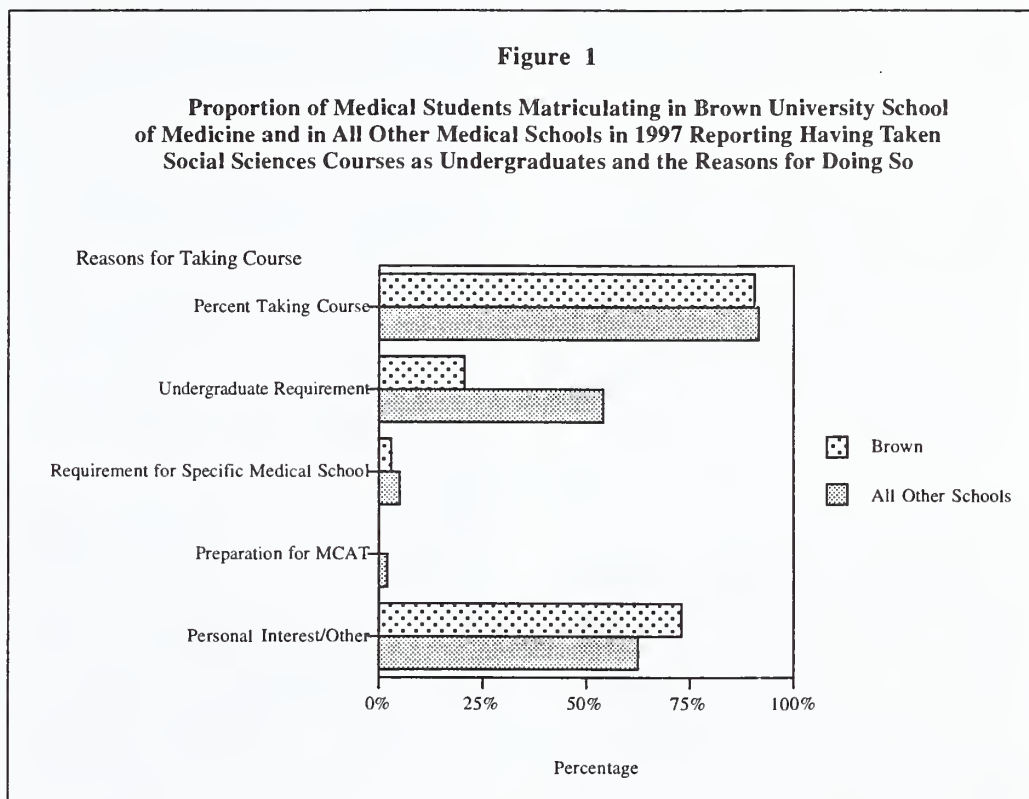
The rest of this article offers an analytical framework and philosophical model that the authors believe would be helpful in the process of considering changes to premedical prerequisites.

PREREQUISITES: A CONCEPTUAL ANALYSIS

The discussion of prerequisites requires attention to the intent of the undergraduate medical education ex-

perience as well as a reconciling of the conflicting issues of in-depth specific knowledge in medical topics versus breadth of experience to provide an opportunity to develop "habits of the mind." These "habits" include critical analysis, receptivity to new ideas and experiences, and comfort in the synthesis of new concepts.

The dictionary defines prerequisite as "something that is necessary to an end or to the carrying out of a function."⁵ In higher education, prerequisites are those courses that students must have already taken prior to enrollment in a specific course. Presum-



ably, these prerequisites are necessary for students to comprehend the material that will be presented and to utilize skills that will be needed in the course. For example, beginning level proficiency in a foreign language is needed before taking a more advanced course that presupposes that all students will already possess basic vocabulary. A course in the fundamentals of chemistry is needed before undertaking more advanced topics in chemistry. These examples are not likely to engender much controversy.

When, in 1910, Abraham Flexner called for medical students to have preparation in biology, chemistry, physics, and mathematics as part of their preparation for the practice of medicine, he wrote during a time when physicians often had not attended any college classes and had little, if any, formal scientific education. Flexner's condemnation of medical education at the turn of the twentieth century led to fundamental changes that resulted in all students having a good foundation in biology, chemistry, physics, and mathematics before entering medical school.

Secondary school preparation at the end of the century, however, is quite different than it was one hundred years earlier. Many students enter college already having taken advanced-level courses in biology, chemistry, physics,

and mathematics. What, then, is the rationale for requiring students to take even more courses in these areas?

Given the level of secondary school preparation, students may not need two more years of chemistry or one more year of physics or one more year of calculus to be able to handle medical school courses in biochemistry, physiology, microbiology, or others.

The potential advantages of a strong science background include greater comfort and ease for the student in the preclinical period. This may be less relevant and applicable as medical schools move to interdisciplinary teaching and problem-based learning. Facts may be easier to master than patterns of thinking and learning that have been enhanced by a broad-based undergraduate educational experience.

If a case cannot be made for the necessity of a prerequisite, are there other reasons that might justify requiring students to take certain courses? One reason might be that by having students take advanced courses in a discipline beyond that which is absolutely necessary would enable faculty to focus on important educational goals rather than having to teach the basics. This reason depends on "important educational goals." Faculty have a natural tendency to be very excited about their own discipline. At times, this may lead to a specialist focus rather than the more integrated approach necessary for the education of an as yet undifferentiated medical school graduate.

In response, some faculty would argue that it is important for all future physicians to be able to probe a subject deeply, beyond superficial understanding, and develop the mental skills of critical analysis and problem solving. This line of argument, however, can't be used to justify requiring students to take a specific course. Students could be required to take a course of their own choice that meets these more heuristic educational goals. Only somewhat tongue in cheek, Lewis Thomas suggested that students should be required to take classical Greek for these reasons.⁶

If the argument is accepted that students should take courses that develop mental skills in critical analysis and problem solving, why shouldn't those courses be science courses? After all, the argument goes, physicians need to be able to think scientifically on a sophisticated level. Taking a basic-level science course and obtaining scientific literacy is not enough. Physicians need to be able to incorporate new knowledge throughout their lifetime and be able to interpret new complex scientific breakthroughs in medicine. Thus, the physician-scientist needs to be able to apply a sophisticated conceptual lens to new knowledge. That takes practice and a deepening scientific understanding over time. Having students enter medical school with a substantial scientific foundation helps them deepen their understanding when again encountered in basic medical science courses as well as in clinical training during the clerkship years and in clinical practice in later years.

This argument has some theoretical appeal, but is not supported by empirical data. PLME students who were science concentrators did not perform any better in medical school or during the first year of residency training than PLME students who were humanities or social science concentrators.⁷ The weakness in the argument may lie in the mistaken belief that the practice of medicine is a science. While medicine applies science in the care of patients, the practice of medicine is not a science itself—it is a healing art. Biomedical research is a science; the biomedical researcher asks questions, generates hypotheses, conducts experiments, and, by using this scientific method, draws conclusions that support or refute the hypothesis. Medicine is not practiced in this way, therefore, it is not surprising that advanced training in science does not convey any special advantage to the medical practitioner."

Likewise, medicine is not a discipline of the humanities or the social sciences or mathematics. Teaching pre-medical students the techniques of textual analysis of Shakespeare will not make them more likely to be humane



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physicians any more than acquiring the anthropologist's skills in ethnographic research will make more culturally sensitive practitioners.

Yet, at some level, the proper education of the physician should include the opportunity to become familiar with the methods of analysis of the humanist, the social scientist, and the behavioral scientist, as well as the natural scientist. Such a broad, liberal education is consistent with the view of medicine expressed in Brown's mission statement: "We teach our students to view the boundaries of medicine to be wide, encompassing all of the factors that lead to human disease, including those of a social, cultural, and economic nature."

Students can become familiar with the modes of analysis of the various disciplines by selecting courses of their own choice. When students are required to take a specific course because of its direct applicability to medicine, then the course should be structured and presented in a way that makes its application to the practice of medicine clear. Even though a student may learn concepts and theories in a course, the student's ability to apply those concepts and theories in a different setting are limited.⁸

An example from a malpractice case illustrates the point. A resident physician was called to see a postsurgical patient who was short of breath. The patient was placed on supplemental oxygen and a blood gas obtained, showing a PaO₂ of 90 mm Hg. When the resident checked with the patient, she said that she was more comfortable. Since the patient was more comfortable and the arterial oxygen was within the normal range, the resident did nothing further. Eight hours later the patient went into respiratory failure and suffered permanent brain damage. The resident had not been able to apply the laws of physics concerning the partial pressure of gases to the clinical situation, thus failing to realize that a "normal" arterial oxygen was not normal when the patient was breathing air with a higher-than-normal concentration of oxygen.

A course designed as "physics for

the physician" could be both useful and popular among premedical or medical students. An example of such a course taught by J. K. Robertson, professor of physics at the Queen's University Faculty of Medicine in Canada, is described by Hayter.⁹ He ascribes Robertson's success to the professor's "sympathetic understanding" of the needs of medical students and his innovative combination of basic and applied science in one course. Some might decry this as "vocationalizing" physics, but if this approach brought physics to life for students and, with it, a better chance that future physicians could apply the principles of physics to their practice for the betterment of their patients, would it not be worth it? At present, premedical students frequently fail to see the relevance of taking physics in college. With such an attitude, the likelihood that students will get much out of the course is diminished.

*We teach our students to
view the boundaries of
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and economic nature.*



While today's medical students are likely to have taken courses in biology, chemistry, physics, and calculus in high school, they are much less likely to have been educated in the social sciences and humanities that may be important for the practice of medicine. Even at the beginning of the twentieth century, Flexner foresaw changing demands for physicians: "But the physician's function is fast becoming social and preventive, rather than individual and curative. Upon him society relies to ascertain, and through measures essentially educational to enforce, the con-

ditions that prevent disease and make positively for physical and moral well-being. It goes without saying that this type of doctor is first of all an educated man."¹⁰

Should medical schools be adding to the list of prerequisites to be sure that premedical students take statistics in preparation of epidemiology and biostatistics, or political science in preparation for the study of health policy, or philosophy in preparation for bioethics, or psychology in preparation for behavioral medicine, or anthropology and sociology in preparation for discussions of culturally appropriate medicine?

In some cases, the answer should be yes. Specifically, statistics would seem to be a much more rational recommendation for premedical students than additional calculus or higher-level mathematics. The medical school curriculum is already overcrowded, so having all students take statistics as undergraduates would obviate the need to build a basic statistics course into the medical school curriculum.

On the other hand, adding prerequisites to the college years erodes the ability of students to pursue a liberal education of their own design. Educators have long argued over the degree to which a college curriculum should be prescribed for students. Early in the nineteenth century, the Yale Report of 1828 laid out the position for the classical education, while Brown University president Francis Wayland argued for a more flexible curriculum. Wayland felt that "every student might study what he chose, all that he chose, and nothing but what he chose...."¹¹

Wayland's position and the Brown tradition garnered support in the late twentieth century in the GPEP report. The GPEP panel recommended that "in framing criteria for admission to medical school, faculties should require only essential courses. Whenever possible, these should be part of the core courses that all college students must take. The practice of medical school admissions committees of recommending additional courses beyond those required for admission should cease."¹²

More recently, the Medical

Schools Objectives Project (MSOP) of the AAMC also lends support to a review of the intent of prerequisite courses. MSOP calls upon medical schools to define the educational outcomes of their medical education programs, then shape their programs to maximize achievement of those objectives.¹³ Brown's competency-based curriculum, **MD2000**, defines nine abilities that it expects of all of its graduates, among which is lifelong learning.¹⁴ Physicians who are lifelong learners are intellectually curious. They accurately perceive gaps in their own knowledge and skills and are able to acquire the additional education they need. They are self-motivated, self-directed adult learners.

If lifelong learning is a goal of the medical school, then the school should create an environment that will promote attainment of that goal. Expecting students to determine their learning needs (with good faculty advising) and empowering them to make the deci-

sions on how best to meet those needs puts lifelong learning into practice from the beginning of the students' education as physicians.

RECOMMENDATIONS

The authors believe that medical schools should approach prerequisites with the goals of promoting lifelong learning, securing a liberal education, and assuring adequate preparation for medical school for college premedical students. The authors recommend that schools follow these guiding principles.

1. When describing the college preparation for medical school, more emphasis should be placed on the habits of mind that are expected and less emphasis on specific course titles.
2. Prerequisites should be limited to only those courses or learning experiences known to be *necessary* for successful performance in medical school.

3. Students should be encouraged to take courses that provide a breadth of experience or the in-depth review of an area of particular interest rather than a series of increasingly demanding "premedical subjects."
4. Lines of communication should be opened between medical schools and departments that provide premedical courses in order to define the objectives of those courses to make them as efficient as possible.
5. Whenever possible, prerequisite courses should be offered that apply concepts in the context of medical practice. This does not preclude students from taking more traditional courses designed to prepare students for more advanced study in that discipline.
6. Medical school courses should be reviewed to see if, with some adaptation, they could incorporate key elements of what otherwise would have been part of a more extensive

A Directory of Clinical Trials

It is with pleasure that *Medicine & Health/Rhode Island* launches a new service to physicians: a directory of clinical trials. In Rhode Island, many researchers—hospital-based and community-based—are conducting clinical trials; but the channels of communication are not optimal. Consequently, sometimes a physician might have patients who would fit into a clinical trial, but the physician doesn't have details. We intend this Directory of Clinical Trials to serve as an information clearinghouse for ongoing trials in the state.

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undergraduate course. For example, basic ethical principles could be incorporated into a medical school course on bioethics rather than having a prerequisite of ethics for all students, or incorporating key concepts of organic chemistry into a medical biochemistry course rather than requiring a separate course in organic chemistry.

7. Medical curriculums should be made more flexible to allow students to meet specific learning needs related to prerequisite knowledge by taking electives during medical school or pursuing independent learning.

CONCLUSION

Premedical prerequisites have come to represent more than just the minimum knowledge and skills necessary for successfully undertaking the medical school curriculum. They can be used as screening devices for admissions, as a means to unload some of the medical school curriculum, and as a way to convey institutional values. Any set of prerequisites can have both salutary and deleterious effects.

Medical schools should be mindful of these various facets when setting prerequisites. As schools reconsider their premedical course requirements it would be appropriate to focus on the following questions: What are the areas of knowledge and skills required of entering students, what attitudes and values should be sought and reinforced, and, how can diversity of educational experiences be retained, recognizing the need for focused knowledge in specific domains? The recommendations of the GPEP report for a broad, liberal education still seem to be the wisest and most prudent path to follow.

ACKNOWLEDGEMENT

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NOTES

*In September 1811, Brown University became the third New England university to establish a medical school, after Harvard (1782) and Dartmouth (1797). During its 16 years of operation, the Medical Department of

Brown University awarded 87 Doctor of Medicine degrees. Yet this auspicious beginning ended on March 15, 1827, when President Francis Wayland required that all university faculty reside on campus, a condition that could not be met by the medical faculty who maintained private practices in the city, resulting in the "temporary" suspension of the medical school, which lasted 136 years.

**Medical schools also produce medical researchers, but that is not the primary mission of most medical schools. Those students who intend to pursue a career in biomedical research are most likely to have been science majors as undergraduates and, at Brown, often pursue a graduate degree, such as the Master of Medical Science or Ph.D.

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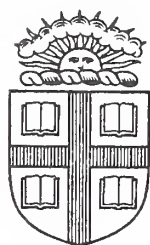
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Brown University School of Medicine, Class of 1998

Stephen R. Smith, MD, Alexandria Morang, Hilary Sweigart, and Janice Viticonte



On May 25, 1998, 76 men and women received the Doctor of Medicine degree from Brown University representing the 24th class of physicians graduated from that institution in this century. If this class follows the pattern of preceding classes, approximately 14% will eventually enter the practice of medicine in the State of Rhode Island. Of the 1,576 physician graduates of previous classes, approximately 221 (14%) are currently licensed to practice in Rhode Island.

The purpose of this article is to introduce the graduates of the M.D. Class of 1998 to the physician community in Rhode Island, since many will be your future professional colleagues.

A PORTRAIT OF THE CLASS OF '98

Thirty graduates were men (39%) and 46 were women (61%). The racial/ethnic composition of the class (Table 1) shows a somewhat higher proportion of students from Asian American backgrounds (37%) than the previous year. About half of the students in the first 4 undergraduate years of the eight-year Program in Liberal Medical Education (PLME) are Asian American. Over 14% of the graduates are members of minority groups underrepresented in medicine (10 African Americans and 1 Native American) as defined by the Association of American Medical Colleges (AAMC). One other graduate is Hispanic. This number is considerably higher than the 2% reported for last year's graduates, reflecting the more successful recruiting of underrepresented minority students in the PLME. For the past 5 years, about 20% of freshmen college PLME students have

Abbreviations Used:

AAMC	Association of American Medical Colleges
EIP	Early Identification Program
PLME	Program in Liberal Medical Education

been from underrepresented minority groups. The percentage of underrepresented minority students in the first 3 years of the medical school is 15%.

Ten graduates are residents of Rhode Island. The Rhode Island students in this year's graduating class came from 7 different communities in the state, with 4 from Providence, and 1 each from Chepachet, East Greenwich, Rumford, Middletown, Wakefield, and Westerly. The high schools from which the students graduated generally reflects this diversity, with 3 students having attended Classical High School and 1 each from East Greenwich, East Providence, Moses Brown, Ponaganset, Queen Anne, and Westerly, with 1 student having attended high school in Iran.

The M.D. Class of 1998 reflects the growing proportion of students from the PLME, with 43 graduates (57%) having come through that route. The second largest cohort of students (14 graduates) came through the combined Brown-Dartmouth Medical Education Program in which students spend their first 2 years of medical school at Dartmouth, then transfer to Brown for the final 2 years.

The medical school entered into special agreements with several postbaccalaureate premedical programs (Brown University, Bryn Mawr College, and Columbia University) shortly after the PLME was inaugurated. Students from these programs decided upon a career in medicine only after completing college. Typically, they have been engaged in other careers for several years following college. The goals in establishing this new route of admission were to maintain a rich diversity in the student body by admitting students who were older and who had different academic and life experiences as well as rounding out the total class size to compensate for the expected attrition from the PLME.

Postbaccalaureate students represented 12% of the graduates. Of the 9 postbaccalaureate students, 4 came through Bryn Mawr College, 1 from Brown, and 4 from Columbia University.

Among the remainder of the class, 8 students were part of the Early Identification Program (EIP), 2 from Providence College, 1 student from Rhode Island College, 1 from the University of Rhode Island, and 4 from Tougaloo College. EIP students are offered provisional admission to the medical school during their sophomore year at their respective undergraduate colleges. The remaining 2 graduates entered medical school through the MD/PhD program and the Brown avenue, the latter being available to Brown students not in the PLME.

Brown University was the most common undergraduate college among the graduates accounting for 45 graduates (59%). Tougaloo College ranked second with 4 members of the Class of 1998. Tied for third with 2 graduates each were Providence College, Wesleyan Uni-

Table 1

Demographic Characteristics of the M.D. Graduates of the Brown University School of Medicine Class of 1998

	No.	Percent
Sex		
Male	30	39%
Female	46	61%
Race		
White	32	42%
Asian American	28	37%
African American	10	13%
Foreign National	4	5%
Hispanic	1	1%
American Indian	1	1%
State of Residence		
Rhode Island	10	13%
New York	21	28%
California	10	13%
Massachusetts	5	7%
Maryland	5	7%
Other Countries	4	5%
New Jersey	4	5%
Mississippi	3	4%
Ohio	2	3%
Other States	12	16%

Table 2
Specialty Choices of the MD Graduates of the
Brown University School of Medicine Classes of 1994-98

Specialty Choice	1994 No.	Percent	1995 No.	Percent	1996 No.	Percent	1997 No.	Percent	1998 No.	Percent
Primary Care, Total	44	54%	41	58%	53	60%	52	59%	46	61%
Internal Medicine, total	23	28%	18	25%	25	28%	16	18%	18	24%
Categorical Medicine	20	25%	15	21%	18	20%	11	13%	13	17%
Primary Care Medicine	3	4%	3	4%	7	8%	5	6%	5	7%
Pediatrics	10	12%	14	11%	10	11%	10	11%	14	18%
Family Medicine	6	7%	4	6%	13	15%	18	20%	10	13%
Medicine/Pediatrics	0	0%	0	0%	1	1%	3	3%	1	1%
Obstetrics & Gynecology	5	6%	5	7%	4	5%	5	6%	3	4%
Surgery	7	9%	7	10%	4	5%	6	7%	5	7%
Surgical Subspecialties, total	8	10%	9	13%	8	9%	10	11%	6	8%
Ophthalmology	2	2%	3	4%	2	2%	2	2%	2	3%
Orthopedics	4	5%	3	4%	4	5%	4	5%	1	1%
Neurosurgery	0	0%	0	0%	0	0%	1	1%	0	0%
Urology	1	1%	3	4%	0	0%	0	0%	1	1%
Plastic Surgery	0	0%	0	0%	1	1%	2	2%	2	3%
Otorhinolaryngology	1	1%	0	0%	1	1%	1	1%	0	0%
Dermatology*							1	1%	1	1%
Emergency Medicine	1	1%	0	0%	3	3%	9	10%	5	7%
Psychiatry	7	9%	3	4%	2	2%	3	3%	2	3%
Neurology	1	1%	2	3%	4	5%	2	2%	1	1%
Transitional and Preliminary	3	4%	0	0%	6	7%	0	0%	1	1%
Institutional Specialties, total	4	5%	8	11%	2	2%	5	6%	5	7%
Anesthesiology	0	0%	3	4%	0	0%	1	1%	1	1%
Pathology	0	0%	0	0%	1	1%	0	0%	0	0%
Rehabilitation Medicine	1	1%	1	1%	1	1%	0	0%	0	0%
Radiology and Radiation Oncology	3	4%	4	6%	0	0%	4	5%	4	5%
Delaying Residency	6	7%	1	1%	6	7%	0	0%	4	5%
Totals	81	100%	71	100%	88	100%	88	100%	76	100%

*Prior to 1997 1st year match in dermatology not possible

versity, the University of California-Davis, and the University of New Hampshire. Altogether, the graduates of the Class of 1998 came from 25 different colleges and universities.

The most common undergraduate major among the class members was biology (including subdisciplines such as neural sciences), with 50% of the class selecting that as their undergraduate field of study. Science majors taken together (including psychology) accounted for 68% of all majors, while 17% majored in the humanities and 13% majored in the social sciences. Among the humanities majors, English was the most common choice, while anthropology was the most popular choice among those majoring in the social sciences. The selection of major among the graduates represents a continuing trend toward a broader range of undergraduate majors, reflecting the larger proportion of postbaccalaureate and PLME students in this class. The postbaccalaureate and PLME students were less likely to be science majors than traditional premedical students.

WHERE THEY ARE GOING

Internal medicine remained the most frequently selected specialty, with 18 students selecting that specialty, although pediatrics placed a very close second with 14 graduates

choosing pediatrics. The proportion of the graduates entering internal medicine is higher than last year (Table 2).

The proportion of the class entering specialties in primary care rose slightly to 61% of the class. This includes the fields of internal medicine, pediatrics, family practice, medicine/pediatrics, and obstetrics and gynecology. Figure 1 illustrates the specialty choices of the Class of 1998.

The actual number of graduates who will eventually practice primary care after completing their graduate medical education training will be smaller than the 61% reported here, if the past is any indication. An analysis of longitudinal data collected by the AAMC of the graduates of the classes of 1987-1991 reveals that over half of the graduates who

*The pattern of career choice
of the MD Class of 1998
reflects the national trend
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subspecialties.*



enter residency programs in internal medicine end up in a subspecialty of internal medicine, such as cardiology. Likewise, about a quarter of those entering residency training in pediatrics will do likewise.

The data for Brown graduates are similar to the national AAMC longitudinal study data. Of those Brown graduates in the MD classes of 1987-1991, only 46% of those entering residencies in internal medicine actually went into general internal medicine practice. In pediatrics, the figure is 59%. Among the primary care residencies, only family practice does not exhibit this pattern. Actually, the number of graduates in those 5 classes who eventually enter family practice is greater than those who started out that way by about 14%. The AAMC data is not very informative about subspecialization in obstetrics and gynecology. The Brown data show that 96% stay in the field of obstetrics and gynecology, but the proportion who subspecialize is not known.

Applying these data to this class, about 31 graduates (41%) will actually practice in primary care. The changing climate in health care delivery is likely to increase that number, as graduates recognize that jobs in subspecialty medicine become harder to find.

A similar trend is seen at the national level. For the fourth year in a row, more than

Table 3

**BROWN UNIVERSITY SCHOOL OF MEDICINE
CLASS OF 1998 RESIDENCY POSITIONS**

Name of Graduate	Hospital Name/Medical School Affiliation	Specialty
Anthony Ahn	Hospital for Joint Diseases/NYU Medical Center	Orthopaedic Surgery
Madhu Ananthakrishnan	Madigan Army Base, WA	Pediatrics
Tanya Becker	Rhode Island Hospital/Brown University	Pediatrics
Chad Brecher	Beth Israel-Deaconess/Harvard Medical School	Internal Medicine-Prelim
	Beth Israel-Deaconess/Harvard Medical School	Radiology
Scott Boyan	Walter Reed Army Medical Center, MD	Psychiatry
Eddy Bullock	Sinai Hospital/Johns Hopkins Medical School	Internal Medicine
William Carey	Stanford Health Services/Stanford University	Pediatrics
Elise Carson	Mt. Zion Medical Center/UCSF	Internal Medicine-Primary
Modassir Choudhry	New York Hospital/Cornell University	Surgery
Sujin Chung	Rhode Island Hospital/Brown University	Emergency Medicine
Kerith Davidson	Univ. of North Carolina Hospitals/UNC	Med/Peds
Michael Diodato	Research	
Krista Dong	Strong Memorial Hospital/University of Rochester	Internal Medicine
George Elias	W. Los Angeles VA Med. Ctr./UCLA School of Medicine	Internal Medicine
Joshua Gady	University Hospitals of Cleveland/Case Western Reserve Univ.	Surgery
Leslie Gordon	Rhode Island Hospital/Brown University	Pediatrics-Prelim
	Massachusetts Eye & Ear Infirmary	Ophthalmology
Carolyn Greene	University of California-San Francisco/UCSF	Internal Medicine-Primary
Nisha Gupta	Barnes-Jewish Hospital/Washington University	Plastic Surgery
Fritz Hofheinz	Brigham & Women's Hospital/Harvard Medical School	Internal Medicine-Primary
Allen Hsiao	Yale-New Haven Hospital/Yale University	Pediatrics
Natalie Hsu	Brown University Medicine Residency	Internal Medicine
Pearl Huang	Lancaster General Hospital/Temple University	Family Practice
Carla Janzen	UCLA Medical Center/UCLA	Ob-Gyn
Mahesh Jayaraman	Santa Clara Valley Medical Ctr./Stanford University	Transitional
	Rhode Island Hospital/Brown University	Radiology
Mary Jennings	Rhode Island Hospital/Brown University	Pediatrics
Andrew Kamell	Lancaster General Hospital/Temple University	Family Practice
Nancy Kaufman	Unknown	
Margaret Kelley	Univ. of Texas Health Science Ctr./San Antonio	Ob-Gyn
Nuna Kim	Mt. Sinai Hospital/Mt. Sinai School of Medicine	Pediatrics-Primary
Leo Kobayashi	Brigham & Women's Hospital/Harvard Medical School	Emergency Medicine
Darissa Kon	Kaiser Permanente Medical/UCLA School of Medicine	Radiology
Gina LaProva	Middlesex Hospital/Univ. of Connecticut	Family Practice
Shoshana Landow	Brown University Medicine Residency	Internal Medicine-Prelim
	SUNY Health Science Ctr./SUNY-Brooklyn	Dermatology
Jennifer Lane	Tripler Army Medical Center	Surgery
Sangwoo Lee	Winthrop University Hospital/SUNY Stony Brook	Internal Medicine-Prelim
	New York Hospital/Cornell University	Ophthalmology
Christine Legler	Walter Reed Army Medical Center	Pediatrics
Wendy Lin	Univ. of Texas Medical School-Houston	Transitional
	UCLA Medical Center/UCLA	Emergency Medicine
Timothy Lynch	Brown University Medicine Residency	Internal Medicine-Prelim
	Washington University	Neurology
Ellen McMahon	Memorial Hospital/Brown University School of Medicine	Family Practice
Myechia Minter	Sinai Hospital/Johns Hopkins Medical School	Internal Medicine
Wanjiku Moite	Northridge Hospital/UCLA School of Medicine	Family Practice
Douglas Nam	Rhode Island Hospital/Brown University	Emergency Medicine
Christopher Nasin	University of Maryland Medical Center	Family Practice
Marjorie Carges Nasin	Walter Reed Army Medical Center, MD	Pediatrics
Michelle Nebres	New England Medical Center/Tufts University	Internal Medicine-Prelim
	Beth Israel-Deaconess/Harvard Medical School	Radiology
Bac Nguyen	Medical Center of Delaware/Jefferson Medical College	Family Practice
Carol O'Shea	Rhode Island Hospital/Brown University School of Medicine	Pediatrics
Phillip Pan	Albany Medical Center Hospital/Albany Medical College	Pediatrics-Primary
Victoria Pao	Stanford Health Services/Stanford University	Plastic Surgery
Patricia Poitevien	NYU Medical Center/New York University	Pediatrics
Delia Radovich	Yale-New Haven Hospital/Yale University	Internal Medicine
Kaditam Reddy	Tripler Army Medical Center, HI	Internal Medicine
Erica Reed	Match Information Withheld by Request	
Shinita Reed	University of Massachusetts Medical School	Family Practice
Elisa Rhew	Beth Israel-Deaconess/Harvard Medical School	Internal Medicine
Elaine Sapiro	Mercy Hospital/UCSD	Transitional
	San Diego Medical Center/UCSD	Emergency Medicine
Farzaneh Sarlak	Memorial Hospital of RI/Brown University School of Med	Internal MedicineMichelle
Schneidermann	University of California-San Francisco	Internal Medicine-Primary
Daniel Schwartz	Research	Research
Linda Shiue	University of California-San Francisco	Internal Medicine-Primary
Rachel Shore	Boston Childrens/Harvard Medical School-Boston Univ.	Pediatrics
Farjaad Siddiq	Rhode Island Hospital/Brown University School of Medicine	Surgery-Prelim
	Rhode Island Hospital/Brown University School of Medicine	Urology
Paul Simmons	Stanford Health Service/Stanford University	Internal Medicine

Table 3 (cont.)

**BROWN UNIVERSITY SCHOOL OF MEDICINE
CLASS OF 1998 RESIDENCY POSITIONS**

Name of Graduate	Hospital Name/Medical School Affiliation	Specialty
Annemarie Spooner	University of North Carolina Hospital/UNC	Ob-Gyn
Helen Su	St. Louis Childrens/Washington University	Pediatrics
Young Su	Univ. of Texas Medical School-Houston	Anesthesiology
Jerrod Taylor	Univ. of Texas Medical Branch-Galveston	Internal Medicine
Hieu Ton-That	Loyola University Medical Center	Surgery
Stella Tsai	Unknown	
George Tsoulfas	University of Iowa Hospitals & Clinics	Surgery
Jim Tung	Cedars-Sinai Medical Center/UCLA School of Medicine	Internal Medicine
Jean Wang	Johns Hopkins Hospital/Johns Hopkins Medical School	Internal Medicine
Paul Ware	San Diego Naval Hospital	Transitional
Michelle Williams	Henry Ford Health Sciences Ctr./Case Western Reserve	Family Practice
Adda Winkes	University of Chicago Hospital	Pediatrics
Phillip Yu	Stanislaus Health Services/UC-Davis	Family Practice

Table 4

**State in Which the First Year of
Residency Training is Located for the
Brown University School of Medicine
MD Class of 1998**

California	16	21%
Connecticut	3	4%
Delaware	1	1%
Hawaii	2	3%
Illinois	2	3%
Iowa	1	1%
Maryland	8	11%
Massachusetts	7	9%
Michigan	1	1%
Missouri	2	3%
New Jersey	1	1%
New York	8	11%
North Carolina	3	4%
Ohio	2	3%
Pennsylvania	2	3%
Rhode Island	12	16%
Texas	4	5%
Washington	1	1%
TOTAL	76	100%

50% of U.S. medical school seniors will pursue training in internal medicine, pediatrics, and family practice, according to the AAMC.¹ (The AAMC does not include obstetrics and gynecology among the primary care special-

ties.) most popular state for residency training. A majority (55%) still stay in the Northeast, while 10% will head to the nation's heartland, and 9% head south.

ties.)

Table 3 lists the Class of 1998 graduates and their residency destinations. Of the 72 graduates who will enter residency training next year (4 are delaying their residencies for 1 or more years), 12 graduates (16%) matched with Brown-affiliated residency programs and will be staying in the state. Boston attracted 7 members of the Class of 1998 for their first year of training and New York City another 8. Los Angeles being the home next year to 5 graduates, San Francisco to 4, Stanford to 3, San Diego to 2, and Davis to 1.

Table 4 lists those states where the graduates will be going for their first year of residency training. The West Coast continues its attraction to 21% of the class. California will be the home for 16 graduates next year and exceeds Rhode Island as the

graduates of residency programs in family practice, pediatrics, internal medicine, obstetrics and gynecology, psychiatry, and emergency medicine were less likely to experience employment difficulty.² However, the rebound in popularity in the West Coast after a one-year dip seems to indicate that the foreboding stories of managed care and scarce job opportunities have not deterred Brown graduates from seeking residency training there.

REFERENCES

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CONCLUSION

The pattern of career choice of the M.D. Class of 1998 reflects the national trend toward careers in primary care and away from subspecialties. This seems to reflect changes in the job market. A recent AAMC survey found that

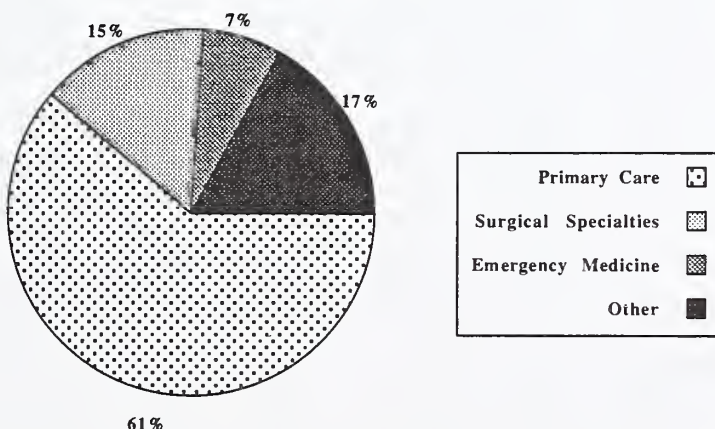


Fig. 1—Specialty Choices of the Brown University School of Medicine Class of 1998

Physicians Newly Licensed in Rhode Island During 1997

Nikki Samaras Deary, Milton W. Hamolsky, MD, and Stanley M. Aronson, MD, MPH

The Rhode Island Board of Medical Licensure & Discipline, a division of Rhode Island's Department of Health, assembles and publishes an annual demographic profile of those allopathic physicians who had been newly licensed by this state during the preceding calendar year. The current description of the newly licensed Rhode Island physicians represents the eighth such report offered by the Board.¹⁻⁷

During the year of 1997, 305 physicians were granted licenses by the Board, in addition to those whose licenses had been renewed from the prior year. The number of new licenses [305], as well as the cumulative number of licenses conferred [3,340] each represent the most physician licenses ever issued by this state. This represents a 3.0% increase in new licenses and a 1.1% increase in total numbers of licenses granted to allopathic physicians [Table 1].

The yearly numbers of licenses granted may not reflect the actual number of physicians actively practicing medicine within the state since increasing numbers of physicians hold valid licenses in more than one state. Indeed, when asked whether they are about to enter the active practice of medicine in Rhode Island, 27.1% of male applicants and 16.8% of female applicants said no. Furthermore, some physicians still in residency training within Rhode Island sought licensure so that they might provide occasional nighttime coverage for practicing physicians ["moonlighting."]

GENDER AND AGE:

The gender and average ages of the newly licensed physicians of this state are summarized in Table 1. Similar data for the prior five years are incorporated

for comparison purposes.

The number of women physicians granted a license has declined slightly after having risen during the prior three years. Women comprised 31.1% of medical licenses conferred during the year 1997, a drop from 35.4% in the prior year. The number of male physicians given licenses continues to rise.

Newly licensed women physicians continue to be a few years younger, on average, than their newly licensed male colleagues. Most of this difference is accounted for by a preponderance of males in the 61 years or older category who had been granted licenses [Table 1]. As in prior years, most of the older physicians entering Rhode Island were recruited for administrative or senior academic positions.

Many physicians receiving Rhode Island licenses in 1997 declare that they are still maintaining offices in other states. Based upon data in their applications, 39 of the 305 newly licensed physicians [12.8%] still maintain offices in Massachusetts, 13 [4.3%] in

Connecticut, 7 [2.3%] in New York and one to three in each of 17 other states as far removed geographically as Oregon and California. Many physicians holding dual licensure in both Rhode Island as well as one of the contiguous states indicate that they have sought local licensure for no more than an occasional consultation; others are establishing satellite offices in Rhode Island but do not anticipate spending much time in Rhode Island.

PLACES OF BIRTH:

The places of birth of the 1997 cohort of newly licensed physicians are summarized in Table 2. In the five years preceding 1997 about 55% of each contingent of newly licensed physicians claimed birth in New England or the Middle Atlantic states. That number has now diminished slightly to 49.8%. New York continues to provide more than any other state [19.7%]. Rhode Island is second with 9.2% of this cohort while Massachusetts provides 8.2%.

Table 1
Physicians Newly Licensed in Rhode Island,
1992 to 1997: Age and Gender

	1992	1993	1994	1995	1996	1997
No. males	130	190	151	180	190	210
No. females	69	69	83	84	104	95
Total	199	259	234	264	294	305
Percent females	34.7%	26.6%	35.5%	35.5%	35.4%	31.1%
Aver. age, males	36.5	37.3	37.6	37.6	37.1	38.2
Aver. age, females	34.2	36.3	35.1	34.5	34.7	34.3
Percent 61 or older						
males	4.6%	1.6%	4.0%	3.3%	4.7%	2.4%
females	0%	0%	1.2%	0%	0%	1.1%
Total no. licensed physicians*	2,835	2,898	3,267	3,286	3,303	3,340

*: No. physicians [M.D.] with active Rhode Island licenses as per January 2 of the year signified.

Table 2**Physicians Newly Licensed in Rhode Island, 1993 - 1997:
Places of Birth**

Place of Birth	1993	1994	1995	1996	1997
Connecticut	8	8	12	12	10
Massachusetts	27	23	31	37	25
Maine	2	0	0	1	0
New Hampshire	1	1	1	0	1
Rhode Island	23	17	17	18	28
Vermont	1	1	0	1	1
New England, total	62 [23.9%]	50 [21.4%]	61 [23.1%]	69 [23.5%]	65 [21.3%]
District of Columbia	5	4	2	3	3
Maryland/Delaware	2	4	4	2	3
New Jersey	14	14	11	17	14
New York	56	45	54	52	60
Pennsylvania	12	13	10	18	7
Middle Atlantic, total	89 [34.4%]	80 [34.2%]	80 [30.3%]	92 [31.3%]	87 [28.5%]
Southern states	16	15	13	10	18
North Central states	9	22	12	14	9
Midwestern states	13	11	22	21	18
Mountain states	5	1	3	4	3
Pacific states	5	10	7	7	8
Remaining states, total	48 [18.5%]	59 [25.2%]	57 [21.6%]	56 [19.0%]	56 [18.4%]
Canada	4 [1.5%]	2 [0.9%]	6 [2.3%]	6 [2.0%]	6 [2.0%]
Countries, other	56 [21.6%]	43 [18.4%]	60 [22.7%]	71 [24.1%]	91 [29.8%]
Total	259	234	264	294	305

About 250 Rhode Island-born individuals are granted the MD degree each year. Since only 28 Rhode Island-born are in the 1997 cohort of newly licensed physicians, the great majority, therefore, must have elected other states as the sites for their practice.

In the 1996 cohort, 71 newly licensed physicians [24.1%] were born in countries other than the United States. This number has risen to 91 [29.8%] in the year 1997. About half of these physicians were born in India or Pakistan. In past years, the majority of Asian-born physicians had been born in the Philippines or Taiwan.

GEOGRAPHIC SITES OF MEDICAL EDUCATION:

Table 3 summarizes the locations of the medical schools attended by the 1997 cohort of physicians newly licensed in Rhode Island. There has been a negligible drop in the relative frequency of United States-Canadian medical schools and a corresponding rise in international medical graduates, particularly those who had attended schools in Asia. Only 1.3% of this group matriculated in the medical schools of western Europe, principally Italy. And only three newly licensed physicians in the 1997 cohort received their medical degrees from Caribbean schools.

Place of birth, as in previous years, continues to be a major determinant in the geographic site of the medical school attended. Of the 164 men with degrees from US-Canadian medical schools, 20 [12.2%] were born outside of the US or Canada. Of the 76 women with degrees from US-Canadian medical schools, 10 [13.2%] were born outside of the US or Canada. Of the 46 graduates of international medical schools, 42 [91.3%] were foreign-born. And of the 19 women with medical degrees from international medical schools, all [100%] were foreign-born. In summary, virtually all Rhode Island-licensed physicians attending international medical schools were born in the country containing that medical school.

The most frequently attended medical schools are listed in Table 4.

Table 3
Physicians Newly Licensed in Rhode Island:
Location of Attended Medical Schools

Year of Rhode Island Licensure Region	before 1992	1992	1993	1994	1995	1996	1997
New England	25.6*	29.4	25.9	24.4	25.1	25.5	23.6
Mid Atlantic	29.3	26.9	31.7	33.3	29.5	29.6	31.5
USA, other	17.1	26.9	19.3	27.3	26.9	22.4	20.7
Canada	2.0	1.5	3.9	0.9	3.4	3.1	3.0
USA+Canada total	74.0	84.7	80.8	85.9	84.9	80.6	78.8
Latin America**	5.4	4.5	5.0	1.7	4.2	4.4	5.2
Asia	5.8	5.0	3.9	3.0	6.1	6.8	8.5
Middle East***	3.5	2.5	3.5	3.4	1.7	3.1	2.6
Africa	0.3	0.4	0.7	0.4	<0.1	0	1.0
Europe, west	8.9	1.5	4.2	4.7	2.2	3.1	1.3
Europe, east	2.0	1.5	1.9	0.9	<0.1	2.0	2.6
Other, total	25.9	15.4	19.2	14.1	14.2	19.4	21.2
No. licensed	2,707	201	259	234	264	294	305

*: percent **: includes Caribbean island medical schools

***: Includes Egyptian medical schools

Table 4

**Physicians Newly Licensed in Rhode Island:
Most Commonly Attended Medical Schools***

Licensed Prior 1993	1993	1994	Licensed In 1995	1996	1997
Tufts	Brown	Brown	Brown	Brown	Brown
Brown	Tufts	State Univ NY**	Tufts	New Jersey***	State Univ NY
Boston	State Univ NY	Tufts	State Univ NY	State Univ NY	Boston
State Univ NY	Boston	Boston	U Mass	Boston	UMass
Bologna	Columbia	Columbia	Boston	Tufts	Georgetown
Georgetown	Pennsylvania	Dartmouth	NY Med	Vermont	New Jersey
Harvard	New Jersey	New Jersey	New Jersey	Georgetown	Tufts
NY Med	Dartmouth	Cornell	McGill	U Mass	Einstein
Vermont	Harvard	Vermont	Yale	Jefferson	Pennsylvania
Jefferson	U Mass	U Mass	Columbia	Einstein	Mt Sinai
Columbia	Jefferson	Geo Washington	Einstein	U Conn	U Conn
Yale	NY Med	NY Med	Georgetown	Pennsylvania	Vermont

*: listed in rank order

**: represents medical graduates of four geographically separated campuses [Brooklyn, Syracuse, Stony Brook, Buffalo.]

***: Represents medical graduates of two geographically separated campuses [Newark and Rutgers.]

Table 5

**Physicians Newly Licensed in Rhode Island: Distribution in Percent
by Gender, Specialty and Year of Licensure**

Specialty	Males					Females				
	1993	1994	1995	1996	1997	1993	1994	1995	1996	1997
Primary care*	29.5	40.4	28.3	39.4	32.3	58.0	63.9	47.6	43.3	63.8
Non-surgical specialties**	26.8	21.9	36.7	21.1	25.8	14.5	14.5	30.0	32.7	20.2
Surgical specialties***	21.6	13.2	15.6	20.0	16.4	10.1	4.8	6.0	11.5	4.3
Emergency medicine	5.3	5.3	4.4	4.2	10.5	4.4	3.6	0	0	5.3
Institution-based specialties+	16.8	19.2	15.0	16.3	15.0	13.0	13.3	16.5	12.5	6.4

*: includes family medicine, general practice, pediatrics, obstetrics/gynecology, and internal medicine without a defined subspecialty.

**: includes internal medicine subspecialties, psychiatry, neurology and dermatology.

***: includes general surgery, orthopedics, ophthalmology, otolaryngology, urology, neurosurgery and plastic surgery,

+: includes pathology, radiology, physical medicine, anesthesiology and administrative medicine.

Of the 12 most frequently attended all are located within the northeastern corridor states [ie, New England, New York, New Jersey, Pennsylvania and the District of Columbia.] In the first few decades of this century, Harvard had been the major provider of physicians for Rhode Island. After World War II, the medical schools of Tufts, Boston

University, Georgetown, Jefferson and Bologna became the major sources for Rhode Island's new physicians. Since 1993, and through the present, Brown has consistently provided the plurality of physicians for this state. The state-funded medical schools in New York, New Jersey, Massachusetts and Connecticut continue to provide significant

numbers of physicians to Rhode Island. Graduates of the Ivy League medical schools, with the exception of Brown and Pennsylvania, are not selecting Rhode Island for practice as readily as they had done in the past.

Eight of the nine New England medical schools are represented in the 1997 cohort of Rhode Island physi-

The pattern of career choice of the MD Class of 1998 reflects the national trend toward careers in primary care and away from subspecialties.



cians as are virtually every medical school from the middle Atlantic states. Indeed, the 240 who had attended US-Canadian medical schools were granted their medical degrees by 75 different US medical schools [in 33 separate states] and six different Canadian medical schools [McGill, Laval, Toronto, Ottawa, Manitoba and Alberta situated in four provinces.]

LICENSURE PATHWAY AND NUMBERS OF ACTIVE MEDICAL LICENSES:

Close to 80% of the new medical licensees were certified by the National Board of Medical Examiners. The remaining licensees presented certification attesting to successful completion of a state-administered FLEX examination.

Applicants for medical licensure in Rhode Island are asked whether they hold active medical licenses in other states or jurisdictions. Amongst male applicants for medical licensure in 1997 71.9% held one or more active licenses elsewhere; five candidates held 10 or more active licenses and one, 24 active licenses. Those with numerous licenses were often employed as locum *tenens* physicians. Amongst female applicants for medical licensure, 56.8% held one or more licenses elsewhere. As noted in prior retrospective surveys, male licensees tended to hold more concurrent state medical licenses than did female physicians. This is a reflection, partially of the younger age of the female physicians [the number of active licenses generally increase with years in medicine] and partially because women physicians tend to be less mobile than their male colleagues.

POSTGRADUATE SUPERVISED HOSPITAL TRAINING:

Applicants for medical licensure in Rhode Island are required to provide the Board with the nature, duration and location of all supervised clinical education undertaken. Male physicians, on average, completed 3.4 years of approved residency training at the time of their application for Rhode Island medical licensure. Women physicians, on average, completed 2.3 years of approved residency training at the time of their application. Since a substantial number of applicants apply for licensure while they are still engaged in supervised residencies or fellowships, these average figures do not reflect the full duration of their graduate clinical education. When, however, the postgraduate experiences of those entering the independent practice of

Table 6

**Newly Licensed Physicians, 1997:
Most Frequently Selected Residency Training Sites**

Rhode Island

Rhode Island Hospital
Hasbro Hospital
Memorial Hospital
Butler Hospital
Miriam Hospital
Roger Williams Hospital
Women & Infants Hospital

Massachusetts

Boston University Medical Center
University of Massachusetts Hospitals
Beth Israel Hospital
St. Elizabeth Hospital

New York

State Univ NY/ Kings County Hospital
Montefiore Hospital

Connecticut

Yale-New Haven Hospital
Hartford Hospital

Maryland/DC

Johns Hopkins Hospital
Walter Reed Medical Center

Table 7

**Physicians Newly Licensed in Rhode Island:
Geographic Location of Residencies/Fellowships**

Location	Residency Training	Fellowship Training
Rhode Island	30.2%	17.1%
Massachusetts	13.8	34.1
Connecticut	7.5	3.7
New York	15.4	10.0
New Jersey	2.6	0
Pennsylvania	6.2	8.5
Maryland/DC	4.6	4.9
Virginia	2.3	1.2
California	2.6	1.2
No. different states	33	17

medicine are reviewed, the years of residency training, on average 3.2 years, are the same for the men and women physicians who are newly licensed.

Fellowship training, typically in one of the subspecialties of internal medicine, was undertaken by 82 of the 305 new licensees [26.9%].

SPECIALTY DISTRIBUTION:

Information on the self-declared specialties and subspecialties of the newly licensed physicians is outlined in Table 5. Women physicians more than their male colleagues have consistently pursued practices in one of the primary care disciplines, particularly pediatrics. On average, about 40% of newly licensed physicians have entered primary care practice in each of the preceding five years. Increasing numbers of women are also entering the fields of obstetrics, ophthalmology, radiology and psychiatry. Males continue to dominate such specialties as orthopedic surgery, reconstructive surgery, urology, critical care medicine and otology.

Table 6 identifies the residency training sites most frequently selected by the 305 newly licensed physicians. Rhode Island Hospital provides the training for substantially more newly licensed physicians than any other institution. The other teaching hospitals affiliated with Brown University School of Medicine also contribute materially as residency training loci for this cohort. Other major postgraduate training sites are located in Massachusetts, New York, Connecticut and Maryland. Military installations such as Walter Reed Army Medical Center and the Naval Medical Center in Bethesda, Maryland, provide a small number [3.9%] of residency programs for this group of physicians. These military training sites are located in California, Texas, New Hampshire, District of Columbia and Maryland.

Table 7 summarizes the geographic locations of the residency training and fellowship programs undertaken by these physicians. In contrast to the wide geographic distribution of the medical schools attended [Table 3] the residency/fellowship programs tend to be located within a few hundred miles of Providence. Over 51% of residencies and 54% of fellowships were completed in Rhode Island, Massachusetts and Connecticut. All of the residency/fellowship training programs were United States-based, in contrast to prior years when an occasional residency or fellowship had been completed overseas.

SPECIALTY BOARD CERTIFICATION:

Table 8 presents numeric data on specialty board certification for those physicians newly licensed in 1997. The percent with board certification was 54.1%, (compared to 55.1% for the 1996 licensees, 51.5% for the 1995 licensees and 51.7% for the 1994 licensees). Those declaring themselves as primary care physicians had a lower certification percentage, largely because many were still in residency training when applying for licensure and were not yet eligible to sit for the certifying examination.



Table 8
Physicians Newly Licensed in Rhode Island:
Board Certification

Specialty	Percent Board Certified
Family medicine	63.6
Pediatrics	42.4
Internal medicine	47.4
Obstetrics/gynecology	38.9
Primary care medicine*	47.7
Non-surgical specialties*	60.5
Surgical specialties*	58.1
Emergency medicine	53.6
Institutional specialties*	59.0
Total	54.1

*: See footnotes in table 5 for definitions.

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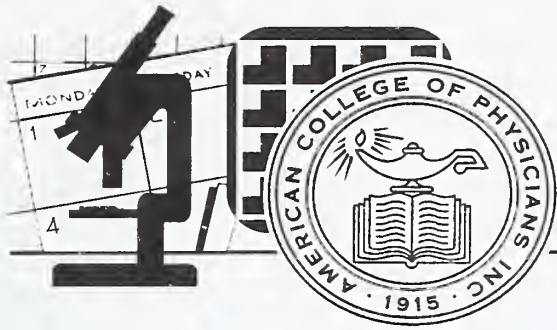
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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Rapid Onset Tardive Dyskinesia (“Fly Catcher Tongue”) in a Neuroleptically Naive Patient Induced by Risperidone

Joseph H. Friedman, MD

Tardive dyskinesia is a term used to describe multiple hyperkinetic movement disorders temporally linked to prolonged exposure to dopamine receptor blocking drugs. For research purposes a minimum exposure of three months¹ is used for uniformity of reporting. The offending drugs have been primarily neuroleptics used for treating psychosis. In the last five years antipsychotic drugs have been developed with fewer extrapyramidal side effects and the term “atypical neuroleptic” has been invoked.² Clozapine was the first such drug and has not been linked to extrapyramidal side effects. The second was risperidone; recently olanzapine and quetiapine have become available commercially. Risperidone, unlike clozapine, has been shown to cause all extrapyramidal side effects but at a lower rate than the “typical” neuroleptics. Several cases of tardive dyskinesia linked to risperidone have been reported^{3,4} and four cases were mentioned in a review of several different efficacy studies of risperidone.⁵ Only rarely was risperidone the only antipsychotic drug taken by the patient. The following case illustrates the possibility of risperidone inducing tardive dyskinesia even when the patient had never previously taken another antipsychotic and despite the fact that the patient had taken the drug only for five months.

CASE

A 44 year old man first came to psychiatric attention in May 1996 for treatment of a paranoid psychosis. His mother had a major mental illness but

the diagnosis was unknown. The patient had a long history of paranoid tendencies but without clear delusions. There was no psychiatric history, use of prescription or drugs of abuse or history of any medical problems other than hypercholesterolemia and hypertriglyceridemia. Brain computed tomography, electroencephalogram with nasopharyngeal electrodes during wakefulness and sleep, routine blood tests and serum ceruloplasmin were normal. When first started on paroxetine 20 mg and risperidone 4.0 mg daily, the neurological exam was normal. About 16 weeks later chewing movements and a slight tremor at rest were noted. Three weeks later oral and buccal movements were noted and the risperidone was reduced. When seen by the neurologist the patient was taking risperidone 2 mg and paroxetine 20 mg daily. He was mildly akinetic with a diminished blink rate and masked facial expression. Mild bradykinesia and rigidity were present but no tremor. Continuous tongue protrusion, usually extending beyond the lips, but no jaw or buccal movements were noted. The tongue movements could be suppressed for up to 30 seconds. The posture was mildly stooped when the patient walked and armswing was mildly reduced but balance was normal.

DISCUSSION

The designation “atypical neuroleptic” has been used in various ways. Initially used to describe the lack of inhibition of amphetamine-induced stereotypy and inability to induce catalepsy in experimental animals,² it has come to be used as

a designation for relative lack of extrapyramidal side effects. In the case of treating patients with Parkinson’s disease the difference between “relative lack” and true lack is important.^{6,7} This case, with the development of the type of tardive dyskinesia called “fly catcher tongue” coexistent with parkinsonism in a patient who had never taken other dopamine blocking drugs unfortunately illustrates that drugs which cause acute and subacute extrapyramidal syndromes will probably also cause tardive ones. Why this patient developed the problem so early in treatment is unexplained, as no primary neurological impairment was found.

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**Rhode Island
Quality Partners, Inc.**

Raymond Maxim, MD

Adult Immunization

Influenza vaccine has been the traditional focus for adult immunization with good reason. The administration of influenza vaccine has the potential to reduce illness, hospitalization and death in at-risk populations. The Centers for Disease Control and Prevention estimates that an average of 130,000-170,000 potentially vaccine-preventable hospitalizations occurred with each epidemic during the flu seasons of 1969-70 and 1993-94. In addition 20,000-40,000 preventable deaths occur each year from influenza infection and complications secondary to influenza. At least 90% of these excess deaths occur in individuals 65 years of age or older. Current vaccines are estimated to be 70% effective in preventing hospitalization for influenza or pneumonia in elderly populations.

The two groups that should be targeted for immunization are those individuals at risk of complications for influenza infection and those individuals likely to transmit infection to those at-risk. In addition, vaccine should be administered to anyone wishing to reduce their risk of infection. Other populations that should be considered for immunization are those who provide essential community services that would be needed in the event of an influenza epidemic. Individuals living in close contact in large groups such as college dormitories and military barracks should be encouraged to get immunized to limit disruption of activities.

Individuals at risk for complications from influenza infection

- Those individuals > age 65
- Residents of any age in nursing homes or other chronic care facilities

- Adults or children with chronic pulmonary or cardiovascular illnesses
- Individuals who have had regular medical followup or hospitalization for chronic metabolic conditions, such as diabetes mellitus, renal dysfunction, hemoglobinopathies, and immunosuppression, including drug related immunosuppression
- Children and teenagers (6 months - 18 years) who are receiving long-term aspirin therapy and, therefore, may be at risk for Reye's syndrome
- Women in the second or third trimester of pregnancy

Individuals likely to transmit disease to at-risk individuals

- Physicians, nurses and other personnel in both hospital and outpatient settings
- Employees of nursing homes and other chronic care facilities likely to come in contact with patients or residents
- Providers of home care (including volunteers) to persons at high risk
- Household contacts (including children) of persons at high risk

The encouraging news is the substantial increase in immunization rates among individuals age 65 and older. The rates have increased from 23% in 1985 to 58% in 1995. This increase is probably attributable to greater acceptance of preventive medicine modalities by physicians and by the more readily

available vaccine given by non-physician health care workers such as nurses and pharmacists. Medicare's decision to include influenza immunization as a covered benefit was also an important contributor to the increase in immunization rates.

Enhanced public awareness and physician acceptance of immunization recommendations can be attributed to efforts of government organizations such as the National Health Service and the Centers for Disease Control for, not only providing guidelines, but, encouraging organizations such as The National Coalition for Adult Immunization. This Coalition provides a forum for local organizations to exchange valuable insight and techniques for improving the effectiveness of immunization campaigns as well as a way to distribute up-to-date information to those involved in local immunization efforts.

In Rhode Island, the Ocean State Adult Immunization Coalition is comprised of 30 member groups. These groups include representatives from Blue Cross & Blue Shield, Rhode Island Department of Health, Rhode Island Medical Society, Rhode Island Quality Partners (RIQP), home health agencies, hospitals, HMOs, vaccine manufacturers, the American Lung Association and members of the lay community.

During the 1997 flu season the Coalition developed a program to improve the immunization rates in Rhode Island. As part of its mission to improve the quality of care for Medicare beneficiaries, RIQP worked closely as a founding member and partner of the Coalition. It was highlighted by an extensive public awareness media campaign that included a press conference where Governor and Mrs. Almond received the first flu shots of the season. The slogan of the campaign was "Get the flu shot. Not the flu." Campaign materials stressed that you cannot get influenza from the flu shot, and promoted the flu shot as a covered Medicare benefit.

In addition, physicians were encouraged to participate in the push to improve the immunization rates among seniors. Prior to the anticipated flu season, physicians were sent a packet including purchasing information for vaccines, a summary of adult immunization recommendations, and information on strategies for improving rates in private practice. This packet also included a copy of the 1994 "National Vaccine Advisory Committee Report" and an informational sheet on immunizations for their waiting rooms.

A second mailing to the physicians urged them to talk to their patients about the benefits of immunization. This letter was endorsed by Patricia Nolan, MD, Director, Department of Health,

Parker Staples, MD, Medical Director, Medicare Division Blue Cross & Blue Shield, Michael Migliori, MD, President, Rhode Island Medical Society, and by Edward Westrick, MD Principal Clinical Coordinator, Rhode Island Quality Partners. The mailing also included a patient postcard reminder, a poster promoting the flu shot, a supply of a special newsletter "For Your Benefit", and Medicare billing information. Practices were encouraged to order additional supplies as needed.

RIQP is currently collecting and analyzing the HCFA claims data to evaluate the success of the 1997 flu prevention campaign. Early data are encouraging but still incomplete. We will compare the data from the 1997-98 influenza season with that from the 1996-97 season. This will demonstrate our anticipated progress and serve as a baseline for the upcoming influenza season. Ultimately we expect a decrease in hospitalization and death secondary to influenza as a result of these efforts.

The Ocean State Adult Immunization Coalition has already begun planning for the 1998-99 flu season. Some of the ideas discussed, and there were many, include promoting pneumococcal immunizations, designing a standardized HMO billing form, and expanding clinic sites to underserved populations. Other topics being considered are standing immunization orders for hospitals, home care agencies and long term care facilities.

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Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD

Contraceptive Methods and Utilization in Rhode Island

Samara I. Viner-Brown, SM, Hanna Kim, PhD, Jana Hesser, PhD, and Cheryl A. LeClair, MSW

Millions of unplanned births and abortions are avoided in the United States each year through contraceptive use.¹ Understanding the contraceptive practices of Rhode Islanders and assuring their access to information and services will result in fewer unintended pregnancies. Currently, a little more than half (53%) of the adult population in Rhode Island is using some form of birth control. Usage varies depending on a variety of demographic factors, including: gender, age, marital status, education, race/ethnicity, and number of children. Economic factors such as income, employment, and town of residence also are correlated with contraceptive use.

Methods

The Rhode Island Behavioral Risk Factor Survey (BRFS) is a telephone survey conducted by the Health Department each year. This survey is sponsored by the Centers for Disease Control and Prevention and asks a variety of questions concerning the behavioral risk factors for the leading causes of illness and death in the United States.

The BRFS conducts telephone interviews each month with approximately 150 randomly selected Rhode Island residents ages 18 and older. Rhode Island's survey was conducted by a professional survey research organization contracted by the Rhode Island Department of Health. In 1996, a minority oversample was taken and a total of 2,482 interviews were completed. Included in the 1996 Rhode Island BRFS was a group of questions related to family planning which covered topics such as contraceptive use, primary contraceptive methods, and place for contraceptive services. These were asked only of persons ages 18 to 55 years.

Results

Of the total number interviewed, 1,703 stated whether or not they were currently using any birth control. Of these respondents, 52.8% stated they were currently using birth control. Figure 1 shows the percentage of respondents who were currently using birth control by selected characteristics. A

higher percentage of the women respondents (57.4%) were using birth control compared with the men, of whom 48.6% were using birth control. Not surprisingly, those of childbearing age (ages 18-44) reported higher rates of birth control usage than those who were older. Over 58% of the respondents of childbearing age were using birth control compared with 32.6% of those past age 45. Unmarried couples had the highest rate of birth control usage at 83.2% compared with only 38.5% of those who were divorced.

Birth control usage varied by race/ethnicity and was highest among Whites and Blacks at 54.8% and 52.7%, respectively, compared with 44.4% of Hispanics and 24.8% of those in other race/ethnic groups. Respondents with children under age 18 had higher rates of usage compared with those who did not have children; for example, 67.8% of respondents with two children used birth control compared with 46.8% of respondents with no children.

Education, income and employment status also appeared to be factors in birth control usage. Those respondents with more than a high school education reported higher rates of birth control usage than those with less than a high school education: 54.7% of those who completed college reported using birth control compared with 37.4% of those who did not complete high school. Similarly, those with higher incomes reported higher rates of birth control

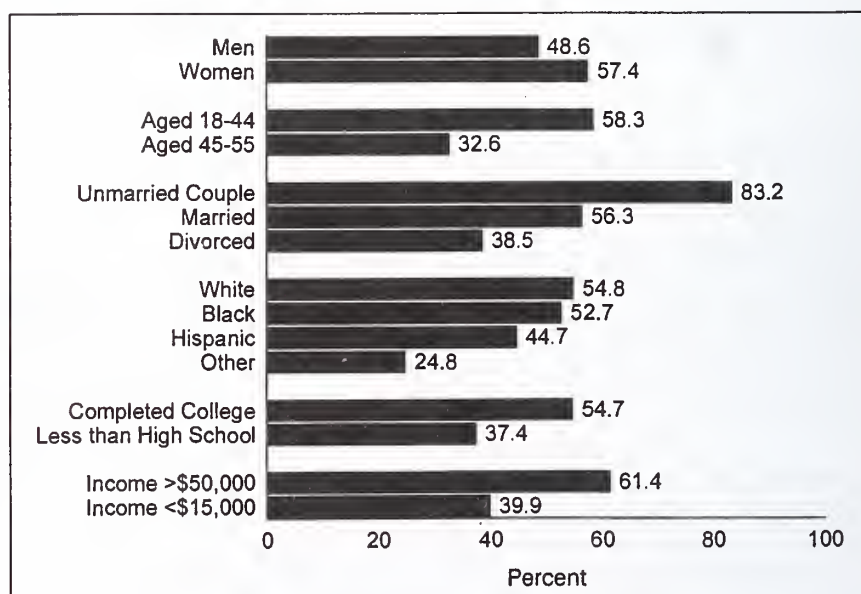


Figure 1. Birth Control Usage by Selected Characteristics, Rhode Island, 1996

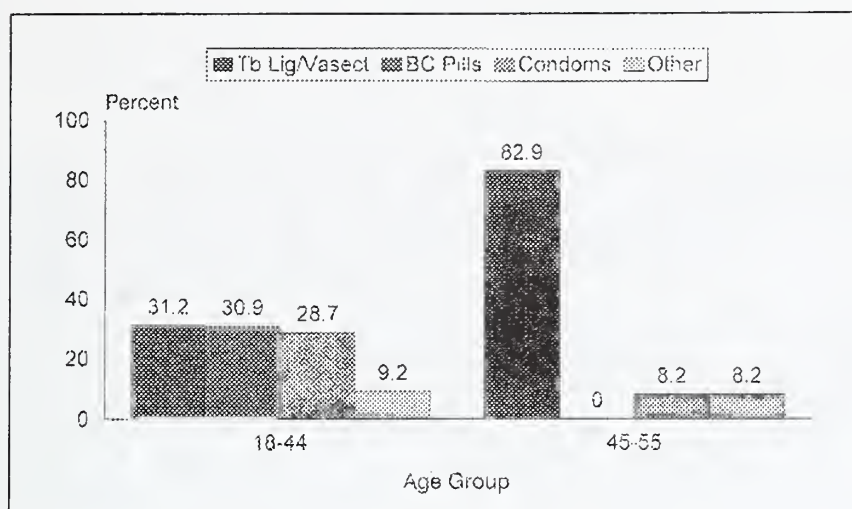


Figure 2. Primary Birth Control Method, by Age, Rhode Island, 1996

use. For instance, 61.4% of those with incomes above \$50,000 were using birth control compared with 39.9% of those with incomes below \$15,000. Respondents who were employed had higher rates of birth control usage than those who were unemployed, 54.3% vs. 43%. Similarly, higher rates were found among those living in suburban towns (55.3%) than those living in the five core cities- Providence, Pawtucket, Central Falls, Woonsocket and Newport (44%).

Whether or not respondents had health care coverage did not appear to be a major factor in birth control usage; 53% of those with insurance and 50.5% without insurance stated they were using birth control.

Respondents who reported using birth control were asked about their primary birth control method. Tubal ligation or vasectomy was the primary method used by 38%, birth control pills were used by 26.9%, condoms by 26%; and other methods, such as diaphragm, IUD, Norplant, Depo Provera, etc. were used by 9.1%. Tubal ligation or vasectomy was the primary method used by 82.9% of those in their post-childbearing years compared with 31.2% of those in their childbearing years. Nevertheless, tubal ligation/vasectomy was still the most frequently reported (31.2%) primary method used by those aged 18-44, higher than birth control pills (30.9%), condoms (28.7%) and other methods (9.1%). (Figure 2)

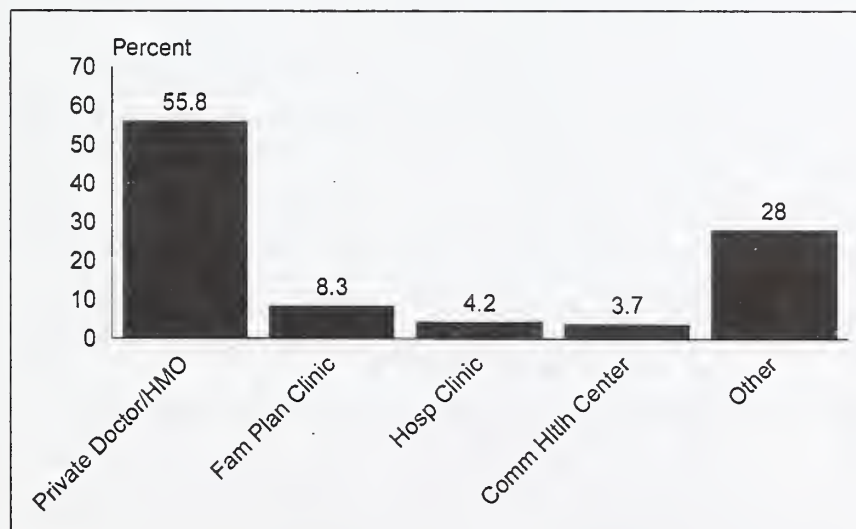


Figure 3. Places for Birth Control Service, Rhode Island, 1996

In terms of the place people went for family planning services, most stated they went to private doctors. Over half of the respondents (53.1%) stated they went to private doctors for their family planning services; 8.3% to family planning clinics; 4.2% to hospital clinics; 3.7% to community health centers; 2.7% to their HMO; and 21.7% to other sources for family planning services, including worksites, community programs, and pharmacies (Figure 3). Although private doctors were the source of family planning services for 31.5% of respondents aged 18-24, almost one-quarter (23.3%) of respondents in this age group stated they went to family planning clinics for family planning services.

Discussion

Understanding the birth control practices of Rhode Islanders will aid the Health Department in assuring that family planning information and services are made available and accessible to all Rhode Islanders. The BRFS data indicate a need to further explore the reasons behind the variations in birth control use by different population groups in order to tailor education efforts to meet their needs. These data also show that the majority of Rhode Islanders obtain their family planning services in their private doctor's office. In the past, the Health Department's Family Planning Program has targeted its education activities primarily in family planning clinics, but will now try to work more closely with private doctors' offices. Additionally, the Family Planning Program is working towards making vasectomy services available to uninsured men, for whom cost is a significant barrier, and which fits closely with the fact that vasectomy and tubal ligation were most often reported as the birth control method.

Addressing the family planning needs of Rhode Islanders remains a challenge. However, working closely with providers and health insurers, and utilizing tools like the BRFS, will result in making family planning information and services more available and accessible to Rhode Islanders.

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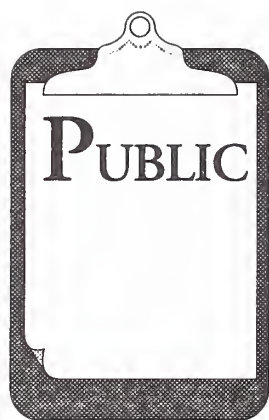
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Palliative Care for Cancer Patients – Current Issues

John P. Fulton, PhD

OBJECTIVE

In 1996 the Rhode Island Department of Health assembled an Expert Panel on Cancer Treatment to advise the Department on revising the State's current cancer control plan, published in 1989.¹ After a series of discussions, the Panel proposed a number of recommendations for cancer care in the State, including two which address palliative care:

- Extend and improve patient access to state-of-the-art cancer care, including early diagnosis, prompt multidisciplinary treatment, and support services.
- Extend and improve application of state-of-the-art cancer care by health professionals, including accurate staging, adequate patient referral for multidisciplinary treatment, aggressive patient follow-up, and appropriate attention to quality of life and support services.

After further reflection, the Chair of the Expert Panel recommended that an Expert Panel on Palliative Care be assembled to address palliative care issues comprehensively. The Department has acted on this recommendation and is in the process of recruiting Panel members. The Panel will be asked to address current issues in palliative care, as identified by the Expert Panel on Cancer Treatment and a recent review of the current literature.

CURRENT ISSUES IN PALLIATIVE CARE FOR CANCER PATIENTS

In 1998, 31 years after the founding of the first hospice by Dr. Cicely Saunders in Great Britain,² and 24 years after the founding of the first hospice in the U.S. (The Connecticut Hospice),³ many terminally ill cancer patients (and other terminally ill patients) in this country still do not receive adequate palliative care. As a result, many experience very poor quality of life at the end of life.^{2,4} Many live and die in pain.^{2,5-7} This failure to meet the needs of the dying has fueled the movement toward physician assisted suicide.⁸

Many reasons have been developed in the literature to explain this complex phenomenon. A few main themes

have emerged, and are listed as "potential determinants of inadequate palliative care for terminally ill patients" in Table 1.

COMMENTS?

We invite your comments on the issues proposed for discussion. Are there additional issues you would like the Expert Panel to address? Are there comments you would like to make on the issues as identified? Please send them in writing to the column editor, Dr. John Fulton, either by e-mail (FULT100W@aol.com), fax (401-861-5751), or mail (Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097).

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Table 1. Potential determinants of inadequate palliative care for terminally ill patients

- Despite increasing recognition of the need to improve the quality of life for terminally ill people, the aggressive pursuit of life-saving measures for terminally ill patients is generally expected and accepted in U.S. society.^{4,9,10}
- Despite the desire to maintain a good quality of life and to die with dignity and without pain, many patients and their families have great difficulty accepting an impending death and opting for palliative care in place of more aggressive treatments.⁴
 - Communication among patients, their families, and providers about preferences for care at the end of life is generally inadequate for informed decision making.⁴
- Advance directives may be too vague to guide terminal care.¹¹
- Advance directives may go unheeded by providers.¹²
 - Communication among patients, their families, and providers about preferences for care at the end of life is generally inadequate for informed decision making.⁴
- Physicians may have difficulty accepting the impending death of a patient and opting for palliative care in place of more aggressive treatments.¹³
- In the main, physicians have inadequate tools for palliative care.
 - Training in palliative medicine is inadequate in most medical schools.^{8,4,12,15}
 - Worldwide, there are few centers of excellence for palliative medicine.¹⁶
 - Palliative care services are not fully integrated into the health care system.^{12,17,18}
 - Few oncology centers offer formal training in communication skills.¹⁹
- Financial incentives and disincentives favor the provision of traditional medical care services over supportive services at the end of life.²⁰
- Hospice care, as developed and financed in the U.S., is inaccessible to many terminally ill patients and their families.
 - In the main, physicians are slow in referring patients to hospice care.¹²
 - Physicians may be unaware of hospice benefits.¹²
 - Physicians may not wish to transfer control of patient care to hospice providers.¹²
 - Current hospice benefits mandate that the patient have less than six months to live.
 - It is difficult to establish an accurate prognosis with certain patients.^{12,13} As a result, many who would have benefited from services earlier in the course of terminal care are admitted within days of death.^{2,21,22}
 - It is difficult for patients and their families to accept an “all or nothing” demarcation between curative care and palliative care. Many cancer patients overestimate their prognoses.²³
 - Few inpatient hospices exist.⁸ In many localities, hospice care is only available as home care, requiring round-the-clock care giving by family members in the home. Some terminally ill patients do not have family members available to support them in this way.^{12,24-26} Others, with severe physical dysfunction, may not be served best in the home setting, given the resources that are generally available for use in that setting.²
 - Hospice care in the U.S. is less accessible in rural and inner-city areas than in other urban and suburban areas.¹²
 - Hospices may not employ sufficient numbers of people from ethnic and racial minority groups, creating a barrier to the use of hospice services by members of those groups.^{12,25,26}
 - Hospice principles of communication may be alien and threatening to people of certain cultures.¹²
- Hospitals and nursing homes, where most terminally ill cancer patients die, may not be prepared to assure effective palliative care for patients in need of it.²
- U.S. society as a whole is uncomfortable with the use of opioids for the treatment of pain.¹²
 - Physicians and nurses fear that patients will become addicted to pain medication.²
 - Education addressing the control of pain in terminally ill patients is lacking in many medical schools and in many schools of nursing.²



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	February 1998	12 Months Ending with February 1998	
	Number	Number	Rates
Live Births	937	13,337	13.5*
Deaths	957	9,947	10.0*
Infant Deaths	(4)	(94)	7.0#
Neonatal deaths	(3)	(77)	5.8#
Marriages	399	8,072	8.2*
Divorces	339	3,268	3.3*
Induced Terminations	413	5,409	405.6#
Spontaneous Fetal Deaths	25	972	72.9#
Under 20 weeks gestation	(21)	(917)	68.8#
20+ weeks gestation	(4)	(55)	4.1#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	August 1997	12 Months Ending with August 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	239	3,412	344.6	3,936.0**
Malignant Neoplasms	196	2,468	249.2	6,847.5
Cerebrovascular Diseases	51	667	67.4	785.0
Injuries (Accident/Suicide/Homicide)	32	339	34.2	6,296.0**
COPD	20	444	44.8	270.0**

**Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.



Book Review: HEADACHES

HEADACHES,

by Egilius L. H. Spierings, MD, PhD

Boston, Butterworth Heinemann, 1998, 246 pages.

ISBN 0 - 7506-7128-9

Pain is the most common symptom which prompts patients to seek health care, and headache is the most common of pain complaints. Indeed, 50% of the population probably experiences headache at least once per month. While headache has been broadly categorized into major types such as tension, vascular, traction, and inflammatory, the etiologies and therapies are fairly diverse, ranging from curative, as in the case of benign brain tumors, to symptomatic, with the use of medications, psychological, and alternative therapies. A comprehensive and concise text on the subject is the goal of this pocket-sized book.

I must admit that, with the current plethora of small handbooks, I was skeptical of the value of this addition to the miniature medical library. I was pleasantly surprised to find, though, that the book was exceptionally well-written and practical. It is not especially comprehensive in scope and depth. For example, there is no mention of benign exertional headaches or the role of the trigemino-vascular system in migraine. It is quite concise, however, and all the really essential knowledge about headaches typically encountered in clinical practice has been distilled by the author.

The book is broadly divided into three sections: acute, subacute, and chronic headache. Under these sections the individual headache entities are described in detail within short chapters, highlighted by lucid and relevant case descriptions. The cases make for enjoyable reading for the person who wishes to read the book from cover to cover. Clinical pearls are generously presented throughout the text. There are many short tables of differential diagnosis and treatment regimens for those in need of quick reference on a specific problem. Statistics regarding efficacy of therapeutic agents as well as their onset of action, duration of action, and side effects are given, which may be particularly useful in counseling patients on expectations from headache treatment.

The field of neurology has often been unjustly criticized as offering little to afflicted patients in the way of effective treatment. This book dispels that myth and describes in up-to-date detail the various treatment options, including comparative results of clinical trials, drug dosages, and recommendations for drug choice based on the literature as well as the author's personal and extensive experience. For example, in the chapter on abortive migraine treatment, the author critically evaluates and compares not only the presently available sumatriptan and zolmitriptan but also the other

serotonin agonist drugs soon to be on the market.

Essential references are included at the end of each chapter for those wishing to read further on a particular subject. This is primarily a practical handbook of clinical neurology which would be of value to any physician confronted by headache problems in the hospital or outpatient setting. In particular, primary care practitioners and emergency medicine physicians will find the book most useful, as well as students and residents-in-training.

— Brian R. Ott, MD

CORRESPONDENCE:

Brian R. Ott, MD

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FIFTY YEARS AGO

❧ [AUGUST, 1948] ❧

William H. Jordan, MD, physician to St. Vincent de Paul Infant Asylum in Providence, discusses the many digestive disturbances encountered in infancy caused by overfeeding of dietary fat. After citing the clinical details of three cases, the author concludes: "Overfeeding of fat in infants fed on cow's milk, or modifications of same, is the rule rather than the exception. Fat indigestion presents an easily recognized condition in an infant which no other element in cow's milk can produce. To prevent overfeeding of fat it is necessary to know exactly how much fat the baby is getting. It is never necessary to give more fat than proteins in cow's milk."

Herbert Terry, MD, describes and discusses two cases of Edebohl's operation of decapsulation of the kidneys for

Bright's disease. The clinical details of two personally supervised cases are presented. In the first, a 37 year-old married woman presented with a lengthy history of renal failure accompanied by many systemic symptoms [headache, dimness of vision, shortness of breath, etc.] Following surgery consisting of renal decapsulation, the patient improved and is free of symptoms although urinalysis continues to show some albumen and a persistently low specific gravity. A second patient, a 47 year old man, also did well postoperatively but died abruptly on the tenth postoperative day presumably from "a dilated heart." The author believes that this procedure "relieves the symptoms and may cure" for the renal failure of Bright's disease. No blood pressures are recorded although the strength of the peripheral pulse is remarked upon.

A case of pneumonia in a male child with hemophilia is described.

FIFTY YEARS AGO

❧ [AUGUST, 1948] ❧

The lead article is a paper on industrial health provided by Professor Philip Drinker of the Harvard School of Public Health, representing the seventh annual Charles V. Chapin Oration. The survey first touches upon gaseous impurities in ambient air, particularly carbon monoxide, illuminating gas and those circumstances which critically reduce the oxygen content of air. The author cites such catastrophic events as the Coconut Grove fire where most deaths were ascribed to asphyxiation rather than the thermal effects of the fire. He then analyzes compressed air illness, sometimes called caisson disease. Next, the author discusses dust diseases including beryllium poisoning, atmospheric lead poisoning and metal fume fever. He then notes the possible injurious effects of X-rays and the hazards in the industrial use of atomic energy. He concludes with an outline of the relationship between labor relations, workman's compensation and industrial health.



Howard W. Umstead, MD, and Walter J. Dufresne, MD, discuss continuous lumbar peridural anesthesia in obstetrics.

TWENTY FIVE YEARS AGO

❧ [AUGUST, 1973] ❧

Alfred G. Knudson, Jr, MD, PhD, discusses the prospects for management, and perhaps control, of certain hereditary diseases. He summarizes, in turn, diseases which are of essentially chromosomal in origin [such as Down syndrome], those which are Mendelian [usually recessive diseases such as the in-born errors of metabolism], those which are polygenic [such as schizophrenia] and those which are somatic. He considers, in sequence, potential mechanisms of control, the role of transduction and cell hybridization, and finally, future prospects for prevention and treatment.

Fredy P. Roland, MD, summarizes studies on *Vibrio parahaemolyticus* in samples derived from Narragansett Bay. Because this organism is capable of surviving in sea water and readily invades marine animals, a potential public health problem exists. The author cites a recent case and urges that this organism be sought for vigorously in instances of gastroenteritis believed to be related to contaminated sea-food ingestion.

Guy A. Settipane, MD, discusses newer concepts regarding pathogenic mechanisms underlying human allergy. He notes that the major defect in atopic diseases may be a defective beta-2 receptor which may be caused by at least one abnormal gene action and hence can account for the hereditary quality of atopy.

A tribute to the poet-physician Ephraim Luzzatto [1729-1792] is presented by Harry A. Savitz, MD.

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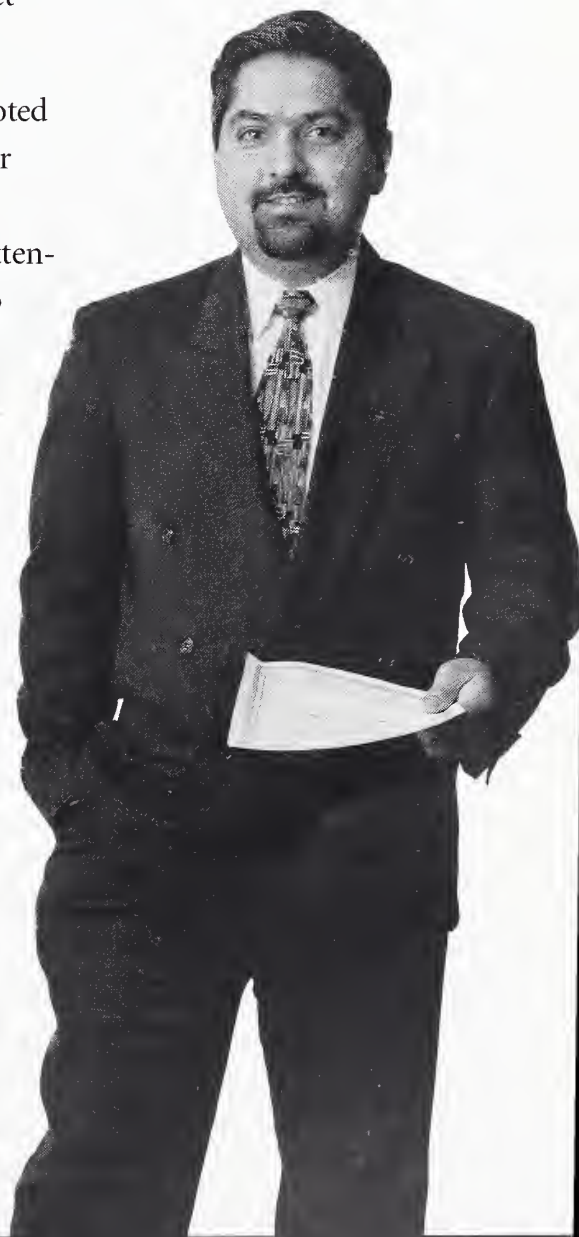
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The World's Mine Oyster



West coast Departments of Health, from British Columbia to California, reported serious outbreaks of food poisoning during the summer months of 1997. Over 200 persons were afflicted with an acute illness characterized by rapidly evolving, explosive diarrhea, nausea, vomiting, chills, fever and headache. All but one of the affected patients recovered uneventfully.

Microbiologists isolated a bacterium, called *Vibrio parahaemolyticus*, from each of these patients. Epidemiologists, seeking a common source of the infecting organism, determined that 90% of the afflicted individuals admitted eating raw oysters within 36 hours of the onset of the illness. This observation then led the state microbiologists to sample specimens harvested from the offshore commercial oyster beds of British Columbia, Washington, Oregon and California. The *Vibrio* organisms were readily cultured leading to closure of the oyster beds and the banning of the sale of raw shellfish in the restaurants of key west coast cities. Following these public health interventions, the epidemic subsided and no new cases arose.

A spectrum of causative agents is involved in food poisoning. Certain bacteria account for about two-thirds of cases. To a lesser degree, viruses, parasites and even chemicals [as in mushroom poisoning] may result in food poisoning. *Vibrio parahaemolyticus*, however, had not been incriminated as an etiological agent of food poisoning until 1953 when Japanese scientists first isolated the organism in a cluster of cases. It was conjectured that the organism was transmitted to humans through the consumption of inadequately cooked fish. Since then, *V. parahaemolyticus* has been identified as the precipitating organism in numerous outbreaks of food poisoning throughout Japan, southeastern Asia and coastal Bangladesh.

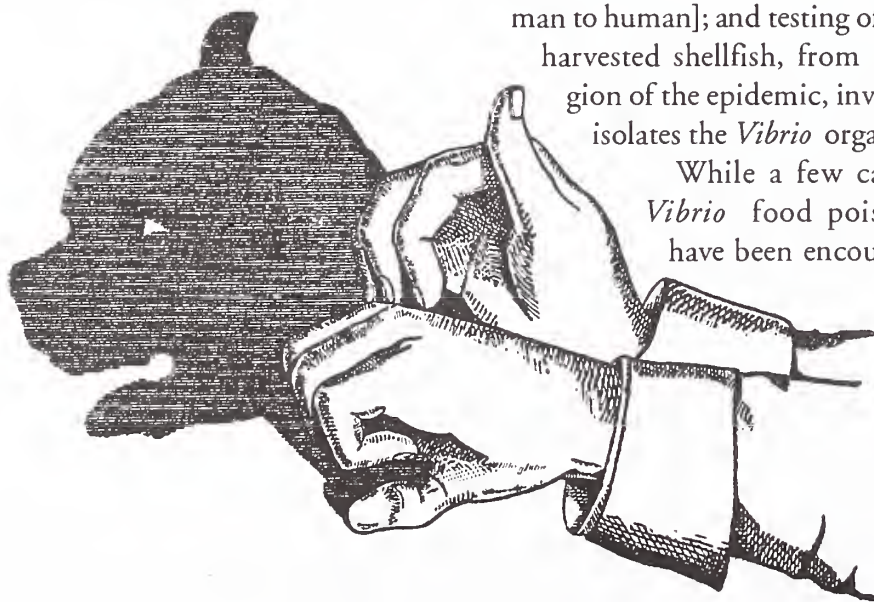
These *Vibrio* outbreaks share the following epidemiological features: They are generally confined to the summer months; cases tend to be concentrated in coastal cities; the victims admit to eating raw or inadequately cooked shellfish, particularly oysters; no secondary cases are recorded [ie, the transmission is generally from infected shellfish to humans with no demonstrated instances of contagion from human to human]; and testing of newly harvested shellfish, from the region of the epidemic, invariably isolates the *Vibrio* organisms.

While a few cases of *Vibrio* food poisoning have been encountered

in those eating cucumbers pickled in marine brine, the overwhelming majority have been associated with the consumption of raw or inadequately cooked shellfish, often insufficiently refrigerated between harvesting and retail sales.

Outbreaks of moderate severity, during the 1980's, had been documented in certain coastal states of the U.S. [Maryland, Washington, Massachusetts, Louisiana], but this country had not experienced a significant outbreak until the Northwest Pacific epidemic of 1997. Scientists speculated on a possible correlation between the increased levels of *Vibrio* organisms within shellfish and a documented rise in Pacific Ocean temperature [warmed, on average, by 2 - 7 degrees Fahrenheit.] In laboratory settings, the *Vibrio* bacteria proliferated more rapidly at moderately elevated temperatures. Public health officials have now conjectured that most oyster beds are contaminated with pathogenic *Vibrio* organisms but, in most cases, their concentration is so low that they will not result in disease unless one of two superimposed circumstances arise: first, that the ocean temperature rises; or second, that the raw oyster is allowed to remain at room temperature for an extended interval before being consumed. In either instance, the *Vibrio* organisms will then multiply, achieving concentrations sufficient to cause clinical disease. The El Nino phenomenon, held responsible for elevated Pacific temperatures, may therefore have far-reaching and unanticipated public health ramifications.

The oyster has been known to man for millenia: as food, as aphrodisiac, and even as metaphor. The Hebrews regarded it as an abomination



[Leviticus 11:41] and hence they were forbidden to eat it. The oyster, however, is not specifically identified by name in the Torah; furthermore, it is unlikely that the nomadic Hebrews struggling through the deserts of Sinai had much intimacy with oyster harvesting.

Oysters were considered great delicacies in Roman times and were prescribed by physicians for those of uncertain or failing virility. A serving of raw oysters for the groom was a commonplace ceremony on wedding evenings. In Mediterranean cultures, the oyster was therefore a widely appreciated symbol of both wealth and po-

tency. The illiterate Elizabethan audience fully understood this when Shakespeare has Pistol say to Falstaff: "Why then, the world's mine oyster, Which I with sword will open."

Yet despite the aphrodisiac promise of oysters, the Elizabethans customarily refrained from eating them during the hot summer months, either because they recognized some causal association with food poisoning or merely because fishermen refrained from harvesting them in the summer lest they disturb the spawning oysters. A contemporary of Shakespeare, William Butler, provided advice which has lingered to this day:

"It is unseasonable and unwholesome in all months that have not an 'r' in their name to eat an oyster."

But 20th century man, not content with rules of prudent behavior, seeks out hazardous encounters:

*Let's sing a song of glory to
Thermisticles O'Shea,*

Who ate a dozen oysters on the second day of May.

— Stanley M. Aronson, MD

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American Medical Residency Programs: An Analysis of New York's "Bell" Regulations and the Training of Physicians

Michael Tobias

In 1984, 18 year-old Libby Zion was admitted to New York Hospital with complaints of fever and flu symptoms. Eight hours later, she died. Sidney Zion, her father and a *New York Times* columnist, filed suit against New York Hospital and the doctors who treated Libby. A grand jury, ordered to investigate the death of Libby Zion and the training of residents in the State of New York, filed its report on December 31, 1986.¹ The grand jury found that the hospital's residents were overworked and therefore might have contributed to the death of Libby Zion. The grand jury recommended that a commission be formed to evaluate residency programs in the State of New York. In 1987 Dr. David Axelrod, the Commissioner of Health, appointed Dr. Bertrand Bell to head the New York State Ad Hoc Advisory Committee on Emergency Services. The Bell Commission, as it is commonly called, consisted of nine distinguished New York physicians. It deliberated for 19 months, and its report became law (New York State Hospital Code Section 405.4)² The Bell Regulations (also called the 405 regulations) stipulated that residents should not work more than 80 hours per week (averaged over four weeks), and not more than 24 consecutive hours. Additionally, interns and residents should have at least one twenty-four-hour period of nonworking time each week and residents should be supervised by attending physicians twenty-four hours a day.^{3,4} For Dr. Bell, the issue of supervision was the most important of the 405 regulations.

This legislation, effective July 1, 1989, was initially ignored by several (if not all) hospitals in New York. One 1990 article stated: "As of yet, New York hospitals have not reached 100%

compliance with all the regulations."⁵ In 1998, the Bell regulations are still disregarded.

California, Connecticut, Hawaii, Iowa, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, Nevada, Pennsylvania, and Washington have discussed or introduced bills that limit hours and require supervision for medical residents.⁶ However, no bills have passed.

BACKGROUND - THE GENERAL DEBATE ON RESIDENCY TRAINING

Over the last decade, the debate over residents' long hours and traditional training has focused on two effects: the effects of long working hours and distanced supervision on patients, and the effects on residents.⁷ Regarding patients, those who oppose the traditional training argue that a tired and unsupervised resident is not capable of delivering quality care. Traditionalists argue that residents' long shifts ensure continuity of care, enabling the resident to follow the patient's progress for at least 24 hours, and reducing the possibility of mistaken transfer of information among residents between shifts. Furthermore, many doctors will argue that forcing oneself to stay awake, and to think under pressure, is integral to becoming a doctor. As one New York doctor stated in a 1996 interview, "There is something special about pushing yourself to work longer and harder than you ever thought you could."⁸ Elevating medical training to a higher level of responsibility and commitment is a popular and persuasive argument for those opposed to regulation of resident training. However, some physicians find this argu-

Abbreviations Used:

DOH	Department of Health
EW	emergency ward
HMO	health maintenance organization
ICU	intensive care unit

ment absurd: "If the rite of passage primarily serves to teach shared responsibility, collegiality, and bonding, then less destructive means, such as requiring residents to spend a week together in the wilderness, could work equally well."⁹ Physicians have reached no consensus in this debate.

If fatigued residents are unable to deliver quality care to patients, then the government seems justified in protecting the well-being of citizens. However, no conclusive studies support the claim that mortality rates will drop if residents are better rested. On the contrary, several studies indicate that sleep deprivation has little or no effect on patient care. One study investigated how sleep deprivation affects cognition, discernment, visual and auditory vigilance, and eye-hand coordination. Researchers found, "... sleep deprivation did not affect overt cognitive or motor performance [and that the correlation between sleep and performance revealed] only trivial effects due to sleep."¹⁰ This study, as well as several empirical experiments, asserts that the "assumption that sleep deprivation associated with usual on-call schedules impairs cognitive and motor performance of residents such that clinical care of patients may be compromised is not supported by [empirical] observations."¹¹ These studies, though, deal only with simple medical tasks (i.e. reading an electrocardiograph). No empirical study focuses on the effects of sleep deprivation on a resident's ability to think creatively, to perform the

most complicated medical tasks, and to make the most difficult medical decisions. Unfortunately, such a study is difficult to undertake in a controlled setting.

Several doctors and politicians have refuted the empirical evidence with common sense arguments, anecdotal experiences, and general medical facts. As one doctor points out, "Biological studies on the diurnal rhythm have clearly demonstrated that the biological clock requires the winding which is provided by sleep."¹¹ Doctors who favor reduced working hours remember 36-hour shifts during their residencies every third or fourth night as horrific and miserable. It seems logical to assume that an individual who has been awake and working for more than thirty hours would be less alert and more prone to make mistakes than someone who has had a good night's rest. In considering the patient's point of view, does it seem likely that he or she would wish to be treated by a physician who has not slept in thirty hours? The common retort to these practical arguments is:

The medical literature is replete with hard data refuting many common sense experiences. For example, common sense tells us that the treatment of severe hypertension with thiazide diuretics should reduce the risks of heart attacks. Indeed, after careful study the opposite has proven to be true.¹²

Nevertheless, many physicians concede that long working hours negatively affected their ability to treat patients. This unresolved debate between science and common sense, medical tradition and liberal philosophy, lies at the heart of the Bell regulation controversy.

In addition to patient care, there is the impact of long hours on residents. Empirical studies show that sleep deprivation negatively affects residents' personal lives and attitudes toward patients. (Dr. Bell: "There is much evidence that residents are often chronically angry, cynical toward pa-

tients, and suffer from depression, suicidal ideation, substance abuse, and interference with their family lives.")¹³ A 1987 excerpt from a resident's entry in an intensive care unit diary read, "1 AM and I'm ready to go to bed: one should never be ready to go to bed in the ICU — you'll always be disappointed. Anyway, I'm on my way to the EW ... when there's a code (cardiac arrest) ... I keep thinking he is blue enough to go to the ICU. I keep hoping he is going to be too blue to go anywhere. Probably a nice man with a loving wife and concerned children, but I don't want that SOB to make it because I've got one special who is going to keep me up 2 more hours. I don't need an intubated, blue, pneumothorax SOB coming to my unit ... I don't want the asthmatic SOB to live if it means I don't sleep. I don't want the special to live if it means I don't sleep. I just want to sleep."¹⁰

This disturbing example almost seems fictional; it is not. Those arguing for limitations on residents' hours and increased supervision point to examples such as this one and emphasize that medicine is about kindness and compassion. Even Paul Starr (*The Social Transformation of American Medicine*), who maintains a skeptical view of the physician's power and authority over patients, concedes: "[Doctors] come into direct and intimate contact with people in their daily lives; they are present at the critical transitional moments of existence. They serve as intermediaries between science and private experience, interpreting personal troubles in the abstract language of scientific knowledge."¹⁴ There seems to be a fundamental error in the system when residency programs cultivate an environment which breeds hatred and contempt.

OPINIONS OF RI DOCTORS - A SAMPLE INTERVIEW

Presently, many doctors feel that much of their authority, sovereignty, and independence has been stripped by HMOs, insurance companies, lawyers, and the government. For some, the Bell regulations exemplify this loss of power; for others, the regulations are a sym-

bolic piece of a much larger problem.

For example, one Rhode Island surgeon expressed skepticism toward the 405 regulations. This physician, who trained about fifteen years ago in the Navy and worked well over 100 hours a week for most of his residency, stated, "[Most doctors] are opposed to arbitrary regulations from outside the profession. There is a problem to some extent, but New York's regulations are not the answer."¹⁵ As to why the regulations are not followed, the doctor answered:

You can't educate residents under those terms. You cannot learn to treat acute illness on a timetable. If an Ob/Gyn resident has a complicated case, he or she won't want to leave when their shift ends; if they are good doctors, they will want to deliver the baby and share that experience with the family. They will want to make sure that the mother and the baby are O.K. before they leave. Good residents won't leave the hospital even if the attending tells them to. And the attending won't — the attending will say "of course you should stay."¹⁵

This doctor is arguing that residents cannot be trained if the hospitals observe the Bell regulations. He does not consider it controversial to declare that the attending physicians and residents must break the law for a successful training regimen. "If a doctor is caught not following guidelines of the Bell regulations, managed care, or any other restriction, he can always take the moral high ground and declare that he was doing what was best for the patient."¹⁵ The laws, the Courts, the public, and medical science all tend to support the doctor.

As for the Bell commission, the surgeon attributed its formation to the highly publicized Libby Zion case. However, he acknowledged that the trend towards reducing the workloads and responsibility of residents was not

new:

"Before I was a resident, all the patients in teaching hospitals were the chief resident's patients, not the attending's. This system created better doctors, but the residents killed a lot more people because of it. And the ritual that evolved was that mistakes were covered up, and the attendings or chief residents would cover for mistakes made by the inexperienced interns and residents. In the late 70s, the attendings started assuming more responsibility because of legal pressures, bad publicity, and rises in insurance costs. Things occur gradually in medicine. As an intern, I always was the one drawing blood, now there are people that do it for the interns. The concept behind the Bell regulations, namely, reducing resident's workloads and responsibility, has been a consistent trend over the last twenty years."¹⁵

Some might find "killing people" and "covering it up" unsettling. But residents-in-training must make decisions and perform procedures; one cannot learn exclusively from watching. Tragically, allowing residents to train on real patients is the most effective way for "doctors in training" to learn. Although residents may learn more in a shorter period of time if they are permitted to make more of their own decisions, other pressures have forced doctors to reduce this "sink or swim" teaching strategy because it is safer for patients. Instead, regulations call for increased supervision of residents and mandate that attending physicians assume increased responsibility for patients.

Most physicians are still confused about the true goal of the Bell regulations. No doctor (except Dr. Bell) whom I consulted mentioned fundamental changes to the purpose of medical residents in hospitals. Doctors talk about sovereignty, arbitrary government controls, and numbers of hours, but they do not consider altering the fundamental roles of residents and attending physicians at teaching hospitals. Dr. Bell has emphasized that supervision was the most important part of the 405 regulations, not the hour restrictions. ("While the need to

change the working hours of house staff has received the lion's share of publicity, the focus of the recommendations of the Bell Committee is on supervision ... The Bell Committee report emphasizes that the responsibility for the patient lies with the attending ... Residency programs, as graduate education, should be run by educators.")

Even today, Dr. Bell insists that most people do not understand that the Commission was trying to fundamentally reform residency training.

... the debate over residents' long hours and traditional training has focused on two effects: the effects of long working hours and distanced supervision on patients, and the effects on residents.



Indeed, the surveys, articles, and interviews show that in nine years, Hospital Code 405 has had little or no impact on residency training. The message of the Bell Commission has blurred into a power struggle between doctors, hospitals, and the government. The goal of Dr. Axelrod, Dr. Bell and the Commission was to alter the culture of the house staff and the traditions of residency training. Unfortunately, this subtle message was missed and ignored when professionals read about the explicit hour limitations. Physicians feared the slippery slope: if the government mandates maximum hour restrictions today, they will mandate more tomorrow.

GOOD TEACHING OR GOOD BUSINESS

Economic factors are another component to residency training. (Paul Starr: "Interns and residents provided hospitals with relatively inexpensive professional labor. The hospitals with ample house staff could do more

thorough workups of patients and perform a variety of functions for busy private practitioners. Without house staff, hospitals could not easily secure coverage at nights and on weekends ... The number of residency positions shot up from 5,000 to over 12,000 between 1940 and 1947 and reached 25,000 by 1955.")¹⁴

Thus, residency programs were created initially to increase the number of patients who could be treated - yielding more money for attending physicians and hospitals. Indeed, Starr declares that, "The profit that doctors and hospitals derived from house staff was one of the driving forces of the postwar medical system."¹⁴ Yet if the traditions of the training process are rooted in economic development, why should they be treated as sacred and necessary to the training of competent physicians? Instead of continuity of care, perhaps the demand for doctors to work at night was the real reason that residents follow a patient for 24 hours.

ARE THE 405 REGULATIONS FOLLOWED?

In 1989, 48 of 77 New York hospitals surveyed by the DOH were found to be violating the Hospital Code. The assumption was that New York's hospitals needed time to adjust.

In November 1994, Mark Green, the Public Advocate of New York, published a report ("How Hospitals Violate the Bell regulations Governing Resident Working Conditions.") which "... documents systematic non-compliance in New York City hospitals with the New York State... 'Bell' regulations."⁶ The number of hospitals violating the regulations increased with time. "From July of 1990 to December of 1991, 17 of 24 (71%) hospitals surveyed were out of compliance. In 1992, 9 of 12 (75%) of surveyed hospitals failed to comply. By 1993 the State Health Department's survey of 12 hospitals found 11 hospitals (92%) in violation of Bell [regulations] ..." ⁶

One possible explanation for this trend toward non-compliance is that, initially, hospitals and attending physicians were wary of the potential consequences of violating the Bell

regulations. But when hospitals perceived no punishments, and no incentives to follow the 405 regulations, they ignored them. John Ronches, a health official, confirmed, "There aren't any real penalties for not complying. Hospitals make up false schedules that comport to guidelines."⁶ Furthermore, once Dr. Axelrod was no longer the Commissioner of Health and Dr. Barbara DeBuono took control of that office in 1995, the threat of enforcement diminished.¹⁶

Green is forceful in his argument because he can attack any hospital or hospital official without fear of retribution. Residents and interns, however, do not have this luxury. As Green points out, residents feel that reporting Bell Commission violations can "jeopardize their careers." The perceived risk of reprisal prevents residents from reporting abuses, or speaking out about violations in their departments. And residents are evaluated by the attending doctors who supervise them and set their schedules.⁶

Physicians have different perspectives on the effects of the Bell regulations. Dr. Thomas Gouge, Director of Surgery at New York University Medical Center, claims that the residents in his program consider the Bell regulations a threat to their education and the care of patients. In the documentary, *Bad Medicine*, he declares, "There's no way you can come into compliance with the letter of [the Bell regulations]." He continues, "Let them put us in jail ... They should accept the realities of this world and Dr. Bell should be sent somewhere else."⁶ Many other directors of residency programs in New York (and elsewhere) share his view, which presupposes that medicine transcends the Bell Commission and New York State's bureaucrat-driven regulations. As Dr. Gary Slater, a general surgeon from Mt. Sinai, remarked, "There is no minor surgery, just minor surgeons."⁶

Dissent, though exists; and many physicians support the Bell Commission regulations. One surgeon: "Among my own medical friends, I know a Boston obstetrics resident who told me she once fell asleep while performing a ce-

sarean, scalpel in hand. (She instantly woke up and finished the operation)."⁶ Dr. Scott Barnett, Residency Director of the Pediatrics program at Mount Sinai Hospital, says, "I agree 1,000% that the Bell Commission is a wonderful thing. In the old days, residents were scut monkeys ... Residents love the Bell Commission."⁶ Interestingly, this doctor, along with some others, feels that the Bell Commission has made an impact on the training of residents. A physician in Dr. Barnett's department, who was a resident before and after 1989 when the Bell regulations went into effect, stated, "No one would trade going back."⁶ These positive remarks on the Bell regulations are somewhat of a rarity; for every hopeful and upbeat description of the Bell regulations and residency training in New York, there are dozens of negative ones.

These optimistic comments, however, are not unfounded. One Director of a New York City hospital revealed that his hospital hired a 405 attending with their "Bell funds" which meant that there was an attending physician for the residents 24 hours a day, 365 days a year.⁸ Indeed, some programs in certain hospitals did change in New York because of the Bell regulations. However, most programs in most hospitals did not change. As one chief resident working in a New York City Hospital in March, 1996 summarized: "We work 36 hour shifts all the time. The Bell Commission is bullshit, it does not exist. It exists only on paper."¹⁷

WHY CAN'T THE REGULATIONS WORK?

The Bell Commission was meant to change residency training in New York; however, it really only changed the Hospital Code. As Dr. Bell admits, "We wanted to change the way people thought about residents."¹⁸ Unfortunately, this did not happen. The

role of the resident did not change at teaching hospitals. Residents are still expected to do all the work largely on their own with as little supervision as possible, work 36 hour shifts, and spend more than 100 hours a week in the hospital. Hospital Code 405 did not change the "rites of passage" mentality of doctors; it did not make those who run hospitals realize that residents need to be supervised and rested.

In general, interns and resident are taught to make decisions on their own and to let the senior residents and attending physicians sleep. This philosophy is incompatible with the Bell regulations. According to the regulations, attending physicians and senior residents are supposed to be supervising and available to ask questions at all times. (Dr. Bell: "The Commission was completely united in its view that residents were not to be treated as doctors, but rather as doctors-in-training."⁶) The nine physicians who comprised the Bell Commission concurred; the bulk of the attending physicians in New York State did not. When the regulations were passed, "... the strongest opponents of the regulations were doctors themselves."⁶ The Bell regulations changed the laws on the books, but not the codes of the profession.

SUGGESTIONS FOR THE FUTURE

Pragmatically, with the rise in health care costs, hospitals may soon hire fewer, not more, residents; and the Bell regulations will be further ignored and violated. The one hospital most likely to comply with the 405

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regulations should have been New York Hospital, where Libby Zion died: in 1990, "the DOH cited [New York] hospital for failure to properly supervise residents in the Obstetrics and Gynecology Department."⁶

The Commissioner of Health, Dr. DeBuono, could enforce the 405 regulations, dole out hefty fines, and ultimately close down hospitals. However, the DOH cannot ignore the economic imperatives. Instead, discourse between hospitals, physicians, and the DOH should be continued. Although there has been some recent activity in March 1998 regarding DOH inspections of 12 New York City hospitals, the discussion of residency reform has been superseded by budget cuts and managed care.¹⁹ Perhaps, politicians, doctors, administrators, bureaucrats, and even the public have put residency reform to the bottom of the agenda because it is such a difficult issue. The death of Libby Zion and the passage of the Bell regulations should not be viewed as a huge success or a huge failure; it was neither. The Bell regulations were the beginning of an important change in medicine.

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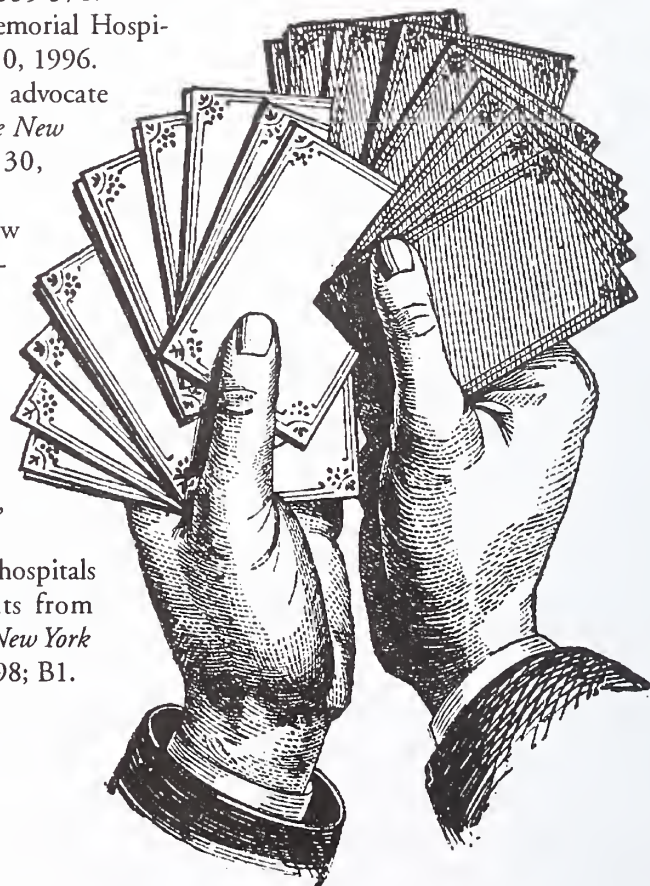
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Are Surgical Residents Allowed to Make Mistakes?

Kavita Babu, Albert Chang, Rochelle Chodock, Michael Klein, Elbert Kuo, Cathia Rene, Robert Shin, Jonathan Smith, and Frank J. Schaberg, MD

Surgical residents must learn the techniques of a skilled surgeon, treat patients, and establish a place in the surgical hierarchy. This endeavor leaves little room for error, yet the inevitability of mistakes in practicing surgery is well-documented. Cohn states, "good judgment comes from bad experiences; bad experiences come from bad judgment. . . the learning of surgery is difficult."¹ Residency directors must control the resident's performance and, simultaneously, create an atmosphere that allows residents room to make errors in the acquisition of judgment and techniques.² Traditionally, however, surgical residency programs enforce perfectionism. Are residents allowed to make mistakes, and what are the consequences?

Mistakes occur. Cohn found 91 errors recorded during a 5-year residency in general surgery.¹ In general, these errors are submitted to peer review. The environment created by peer review and competition has an impact on the surgical residents with respect to their mistakes and those of their peers.

This study seeks (1) to examine the ethical decision-making of surgical residents in response to their own mistakes, (2) to determine the residents' perceptions on assignment of blame after an error, and (3) to identify the criteria residents use in judging the severity of a peer's mistake.

METHODS

A three-page questionnaire consisting of thirty-one multiple choice questions was developed to explore the following areas: concealing information, gender differences in accountability for mistakes, responsibility for surgical mistakes, and appropriate punishment for surgical error. To ensure confidentiality, residents were not required to give their names or other identifying information, except for their age, surgical specialty, year of training, and gender.

In 1996, the questionnaires were distributed to all of the surgical residents in a university-affiliated residency program.

RESULTS

Of 15 respondents, 13 were male and 2 were female. The mean age was 28.9 (with a range of 26-34 and a median of 28). Eleven respondents were in general surgery; 3 in preliminary orthopedics, and 1 in preliminary ophthalmology. Six respondents were PGY-I, 4 were PGY-2, 2 were PGY-3, 2 were PGY-4, and 1 was PGY-5.

In response to the questions about the resident's personal ethics regarding errors, responses were scored as never, rarely, sometimes and frequently.

As Figure 1 shows, 40% of respondents stated they had never concealed information from a patient regarding a mistake; but half admitted admitted to sometimes, or rarely, con-

cealing a mistake.

Two-thirds of the residents said that they had never concealed information from other physicians. [Figure 2]. A majority of the respondents reported that it was never appropriate to claim to have performed a task they planned to do later, but 40% answered that they rarely claimed this, or admitted they sometimes did. Most residents conceded that competition rarely, or sometimes, increased mistakes.

Figure 3 breaks down the perceived incidence of errors by different levels of training. Interns were considered most likely to make mistakes; and responsibility for errors was most often blamed on them. Respondents felt that chief residents were the most likely to blame others for mistakes that they themselves committed.

Figure 1: The incidence of surgical residents concealing mistakes from patients

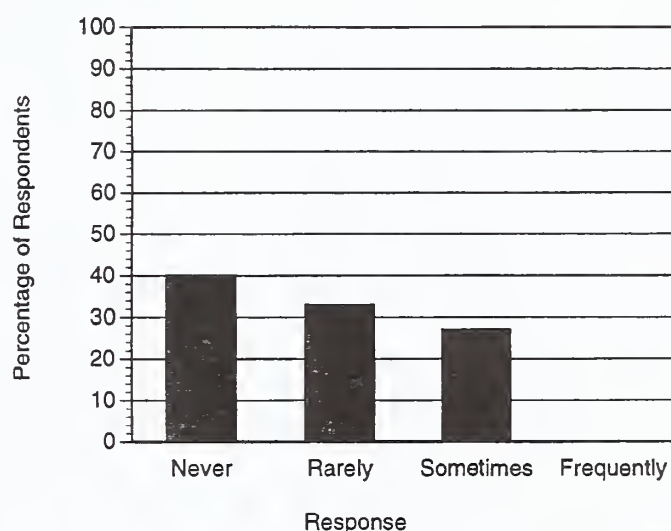
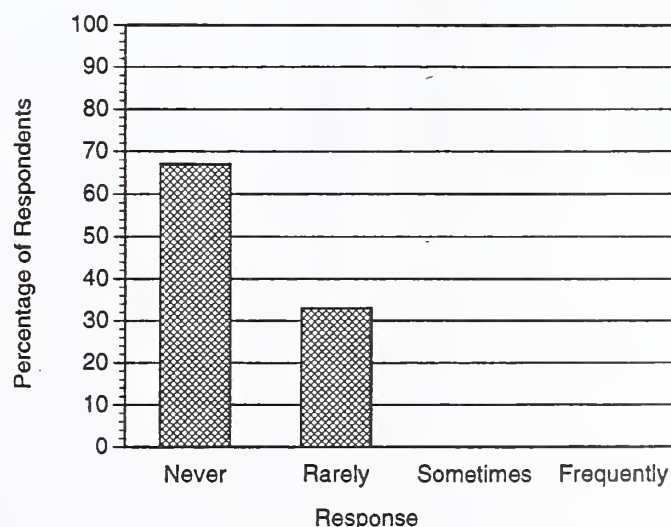


Figure 2: The incidence of surgical residents concealing mistakes from other doctors



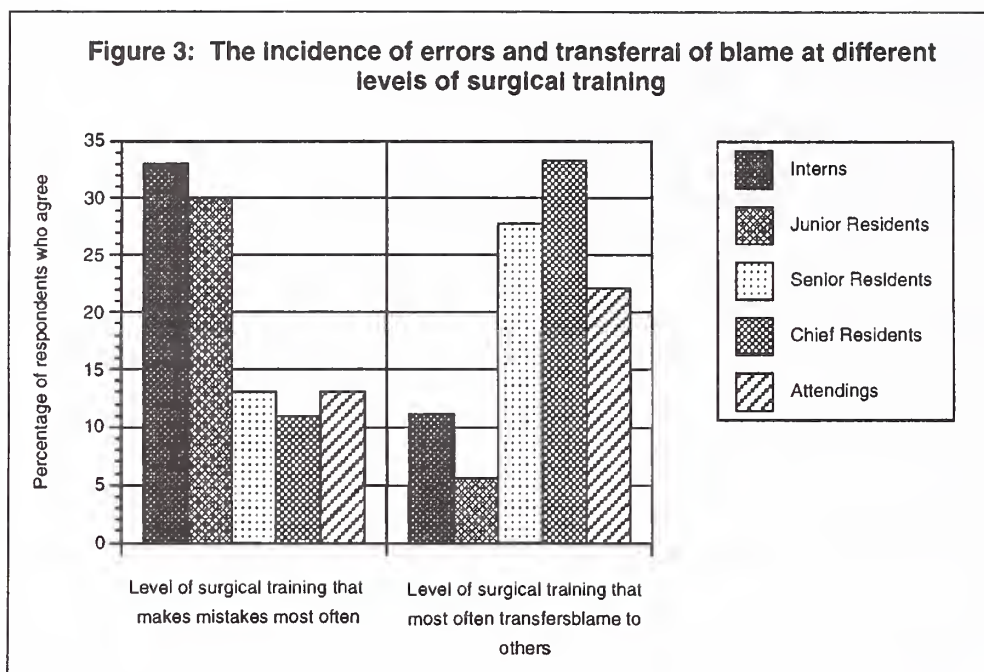


Figure 4 breaks down the criteria used to judge the severity of a peer's mistakes: All respondents ranked the harm to the patient as very important, followed by the nature of the error. Most respondents also considered the resident's acceptance of responsibility for the error very important.

Figure 5 charts respondents' assessment of six errors, factoring in "no harm to patient" or "harm to patient." These errors included forgetting to order a vital diagnostic test, being too tired to check on the status of a patient before leaving for the night, misreading a diagnostic test,

proceeding with a complex procedure for which the resident was technically unprepared, rushing a basic surgical procedure, and making a technical error during a basic surgical procedure. Punishments ranged from nothing to written reprimand and dismissal. Respondents wanted more severe punishments for instances where mistakes led to patient harm; no mistakes warranted dismissal, even when patients suffered harm.

The most frequently advised sanction was a verbal warning.

DISCUSSION

Greenburg stated, "According to both attending and resident surgeons, the most important personality trait for success in a surgical residency is the ability to admit error."³ These resident-respondents had concealed information about errors at some point during their graduate medical education. They were more likely to conceal information about their errors from their patients than from other doctors. In addition, most of the respondents believed it wrong to claim that

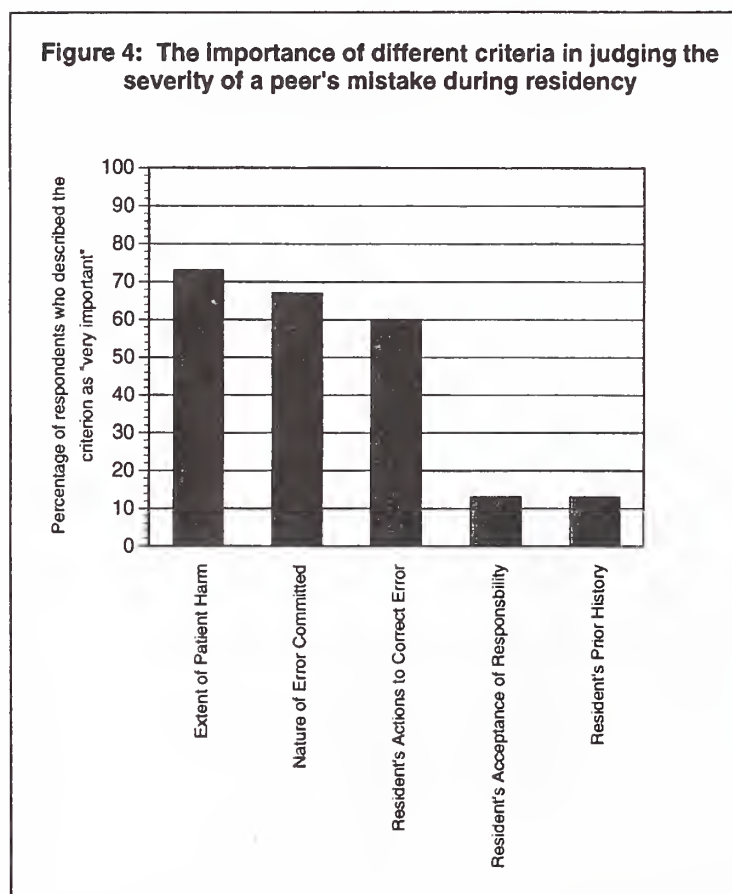
they finished a task they planned to complete later. However, 40% of the residents thought this claim may be appropriate in some situations. Sheehan et al found that 30% of the medical students had observed residents falsifying information (such as reporting that a roentgenogram had been performed when in fact it had not), covering up unethical behavior, and covering up mistreatment of patients in one hospital.⁴ Concealment of error is surprising, considering that the ability to admit one's mistakes has been cited as a marker for success in surgical residencies.

Most of these residents believed that competition among residents contributed to increased mistakes. This finding is interesting because historically many surgical residency programs have been based on a pyramidal system, encouraging resident competition.

There was a consensus that neither gender makes more mistakes during surgical residency. In addition, a majority believe that there is no gender inequity in the assignment of blame for mistakes. This data is consistent with the study of Hayward et al, which found no significant difference in the evaluation of male and female surgical residents in six categories (ethics, judgment, technical skills, knowledge, interpersonal skills and work habits).⁵ (However, our results may have been skewed by the preponderance of males in the sample, since other studies have noted that females on surgical services perceive an unfavorable bias.)^{6,7}

Most feel that interns and junior residents commit the most mistakes and are consequently held responsible. Interestingly, those in higher positions in the surgical hierarchy were more likely to blame others for mistakes they committed themselves.

The key criteria in determining the severity of an error committed by a peer was the extent of harm to the patient. The resident's acceptance of responsibility for the error and the resident's prior history were considered least important. In short, residents evaluate peers' mistakes on outcome, rather than the nature of the error or the resident who commits it. Furthermore, when presented with specific errors, our survey graded the severity of the punishment according to the extent of harm to the patient.



	NO HARM					PATIENT HARM				
	None	Verbal Warning	Demotion	Written Reprimand	Dismissal	None	Verbal Warning	Demotion	Written Reprimand	Dismissal
Forget Test	7	93	0	0	0	0	73	27	0	0
Patient Neglect	7	79	14	0	0	0	20	73	7	0
Misread Test	20	73	7	0	0	7	66	20	7	0
Unprepared	7	39.5	46.5	7	0	0	14	72	14	0
Rush	13	67	13	7	0	0	47	40	13	0
Technical Error	46.5	46.5	0	7	0	20	40	33	7	0

FIGURE 5: Appropriate punishments for error (expressed in percentages) based on NO PATIENT HARM vs. PATIENT HARM

The errors on the survey can be classified as "judgmental," "technical," and "normative." Forgetting to order a diagnostic test and proceeding with a procedure for which the resident is unprepared are "judgmental errors." Misreading a test result and making an error during a basic procedure are "technical errors." Being too tired to check on the status of a patient before leaving for the night and rushing a basic procedure qualify as "normative errors," which represent violations of the unwritten code of conduct of house officers. Cohn found judgmental errors occurred more frequently than either technical or normative errors. Out of ninety-one errors recorded during a 5-year residency in general surgery, he found 79% were judgmental, 15% technical, and 6% normative.¹

In addition, our residents' perceptions of appropriate punishment for error is actually more severe than what has historically occurred. A review of dismissals of categorical residents from the surveyed program showed that three had occurred in a five year period -- all for a pattern of inadequate performance, none for a single episode. There had been no demotions and only one formal written reprimand.

In summary, most of the respondents felt that concealing information on errors was wrong; however, some of the residents had concealed at some point. Most residents also felt that competition could lead to increased mistakes, but only rarely. Almost all of the residents believed that gender did not influence mistakes, nor was either gender blamed for more mistakes, although this may reflect a sample skewed to males. The frequency of errors committed and the blame for errors committed both appeared to decrease as experience increased, although most of the

junior staff appeared to receive a disproportionate share of the blame compared to their perceived number of errors. The extent of patient harm, the nature of errors committed, and the resident's corrective actions were all considered important in judging the severity of a mistake, while acceptance of responsibility and prior history were viewed as less important. In a setting in which a patient was unharmed, most residents believed a verbal warning was the most appropriate response to the varying types of errors; however, more severe punishment (demotion) was considered at least as appropriate when a resident performed a procedure for which he was technically unprepared. Dismissal was never considered appropriate.

Good judgment comes from bad experiences; bad experiences come from bad judgment...the learning of surgery is difficult.



While it is difficult to quantify something as subjective as perceptions of errors, the results of this survey indicate some general trends among the subjects surveyed. Residents' varied responses to many of the questions demonstrate ambiguity in the morality of many important topics related to surgical error. This is particularly significant in surgery, where some error is inevitable. Subsequently, a forum or discussion within a residency program might address the program's policy toward error and the appropriate behavior and punishment for different errors. Such a protocol might prevent many of the non-technical errors and allow a

clearer understanding of the consequences of errors.

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Point of View: Reflections on a Half-Century of Practice

Arthur M. Phillips, MD, FACP and Robert S. Crausman, MD, MMS

Arthur Phillips, MD, this year's recipient of the American College of Physicians' Irving Beck Award granted for lifelong dedication to patients and scholarly pursuit of medicine, recently addressed incoming interns at Memorial Hospital, offering his reflections upon the evolution of the practice of medicine over his very productive career. The key points of his address follow.

— Robert S. Crausman, MD, MMS

INTRODUCTION

In a medical career spanning more than 50 years, I have been witness to a tremendous expansion of knowledge. Its rate of increase can only be described as geometric, with wondrous technologic advances and a myriad of socioeconomic changes that have all been major, ongoing factors in the evolution of the practice of medicine. Throughout, there have been many examples that involve individual physicians that dramatically impact upon patient care. During my life, I have witnessed the identification of the causative agents and recognition of the pathogenesis of many illnesses that once plagued my patients and frustrated the best efforts of physicians. The appreciation of the infectious nature of peptic ulcer disease and cat scratch disease, the elucidation of the metabolic underpinnings of diabetes mellitus, and the determination of the molecular biology responsible for hypertension, vascular disease, hemochromatosis, and breast cancer represent just a few of the more recent examples. Further, physicians have come to understand the clinical course of many diseases in light of a patient's relative life expectancy and the mechanisms whereby such factors as age effect medical treatment. The science of epidemiology has provided many insights into the hereditary nature of many illnesses as well as the role the

environment, occupational history and socioeconomic climate play in both health and disease. The methods whereby illnesses are diagnosed and treated have expanded phenomenally. Technology now allows for the direct visualization of many body parts, the measurement of function on many levels and we, as a discipline, have even witnessed the application of cellular biologic techniques upon the individual cells of a patient, as in the case of reproductive biology. The successful use of this technology is probably best typified by the advent of intensive care units which allow us to effectively care for a wide range of patients in fashions never before possible. For physicians, this vast knowledge and technology can be as overwhelming as it is empowering; and it is incumbent upon doctors now in training to master an ever expanding knowledge base while endeavoring to preserve the humanity and compassion that have so characterized our profession.

Perhaps the most significant evolutionary change to current medicine is the dramatic shift from illness-oriented care of patients in hospital set-

*Doctors of the future
will have to embody
many roles beyond those
of the traditional
physician. They will also
have to be team leaders of
multidisciplinary health
care groups and patient
advocates with many
third parties.*



Abbreviations Used:

PPD purified protein derivative

tings to preventive medicine and health maintenance in outpatient settings. In addition, many illnesses historically managed exclusively in inpatient settings are now commonly cared for at home. Although this shift has been driven by dramatically escalating costs, this emphasis has shed new light upon patient values and physicians' responsibilities, which has been for the betterment of patient care.

The role of physicians in delivering health care has also undergone considerable change during my career. The physician is no longer the sole and exclusive provider of health care. A host of collaborative care providers truly enhance the ability of physicians to care for their patients. The growing role of nurses, therapists, social workers and physical therapists only underscores this point. Unfortunately, there also has been a major intrusion of third parties into the care of patients and physician-patient relationships that does not necessarily improve the care rendered. Managed care, insurance companies, hospital administrators, certain state and federal legislation and in some cases even health departments have at times seemed to have acted counter to this purpose. Doctors of the future will have to embody many roles beyond those of the traditional physician. They will also have to be team leaders of multidisciplinary health care groups and patient advocates with many third parties.

To an intern in 1998, I would ask the rhetorical question, "What do all of these changes mean?" and offer these six points as a basis for starting your own exploration as you grow as a physician. First, standards of care have been developed by many thoughtful expert

panels for various illnesses and for health maintenance. In recent years we have been fortunate to see a shift from traditional consensus-based recommendations towards real evidence-based guidelines. This is a scientific approach we should all favor. A practicing physician needs to learn, evaluate and follow such appropriately developed guidelines.

Second, decision analysis and the use of truly current knowledge of medicine, economics and human values to guide step by step management of certain problems have been of great benefit to physicians and patients. It has found application in both diagnostics and therapeutics. Examples abound such as the evaluation of the thyroid nodule, the positive PPD, and other very common maladies. It has forced physicians to consider the risks and benefits of all treatments. It has brought to physicians' attention the fact that every treatment has a downside risk that needs to factor into decisions and has cast new light upon the fundamental ethical principal of nonmaleficence - first do no harm. Decision analysis also considers the cost effectiveness of particular interventions as well as the optimal use of a limited health care resource. My personal caveat, however, is that the use of statistics in an individual case is always fraught with difficulty. For an individual the statistic often reduces to either 0% or 100%. Never forget that healthcare is not just a commodity and that individual patients are always more than statistics.

Third, aging and caring for an aging population will be a major focus for physicians in the next century. Aging produces a host of physiologic changes which have been collectively described as homeostenosis. This limiting of physiologic reserve in many systems leaves elders more prone to many diseases of old age. Further, a lifetime of environmental and occupational exposure raises the risk of many other conditions. Young physicians need to develop a facility in the science of gerontology and the clinical practice of geriatrics. They also need to be well-grounded in ethically based medi-

cal decision making as there are often no easy answers.

Fourth, the patient-centered focus of modern healthcare and the involvement of patients and their surrogates in health care decisions have been relatively recent developments. Physicians are no longer the autocratic beneficent consultants. In recent decades, we have seen a shift towards the emphasis upon the autonomy of patients, their right to be informed and to refuse. Their personal wishes and needs must be of paramount importance in the decision-making process. The role of the physician has truly been extended to include the responsibility to educate, communicate and advise.

Fifth, preventive medicine is crucial. To prevent or postpone an illness is much better than to treat one that is already established. The use of immunizations has dramatically reduced the incidence of many illnesses that once plagued my patients. The focus of preventive medicine upon health maintenance through examination and screening for preventable conditions is not only the wave of the future but the current state of the art.

Sixth, some things are timeless; they should not change regardless of the external or internal pressures brought to bear upon physicians. Physicians must be held to the highest of standards. They must endeavor to be honest and truthful. They should be industrious and eager to acquire and use new knowledge and skills. They must maintain a high degree of personal and professional integrity and always endeavor to do what is best for the patient. They must accept responsibility and carry out their obligations first and foremost to their patients, but also to their coworkers, hospital and community. They must never forget the importance of their own personal health and the needs of their family. Physicians must be caring and remember that each of their patients is a person. Physicians must adhere to high standards of conduct in both their professional and personal lives. Throughout, physicians must try to understand themselves and how and why they respond in a given circumstance so as to

be more effective in the care of patients. Finally, it has been said that it takes knowledge to be smart. Physicians must always strive to learn and improve throughout their lives.

As a physician, I expect that you will enjoy the continuing pleasures of intellectual challenge as you acquire new knowledge throughout your career. You will have the satisfaction of being needed as you help others who are in need. You will have the respect and friendship of coworkers, and will be able to associate with wonderful people. Interns of the Class of 1998/1999, I congratulate you on your accomplishments and wish you well as you embark on what I know will be wonderful careers.

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Applying a Readiness Model to Increasing Organ Donation and Transplantation

Mark L. Robbins, PhD

Organ transplantation has developed from an experimental therapy to a highly effective treatment for end-stage organ failure. Unfortunately, demand for solid organ transplants has increased at a higher rate than the supply of organ donors. From 1988 to 1996 the number of people on the United Network for Organ Sharing (UNOS) transplant waiting lists rose from 16,026 to 50,047 (312%), while cadaveric donors only increased from 4,080 to 5,421 (33%). As of June 30, 1998, there were more than 56,000 patients on the UNOS waiting list.

Several obstacles to increasing the cadaveric donation rate exist: a) few individuals document their intention to become organ and tissue donors; b) many who document their intention to donate fail to inform their family members of this decision; c) many healthcare professionals offer inadequate information and support for families to choose to donate a loved one's organs and; d) approximately half of the families of potential cadaveric donors refuse to donate. These obstacles have remained despite efforts to educate the public and professionals about the benefits of organ donation. Clearly new approaches are needed.

One of the most promising innovative approaches to behavior change is the Transtheoretical Model (TTM), which matches interventions to each individual's stage of readiness to take action, such as consenting to donation.¹ Interventions based on this model have demonstrated significant impacts on various health-related behaviors in a variety of populations.² This paper briefly reviews factors that influence organ donation, describes the Transtheoretical Model of behavior change and explores its use for increasing the rates of donation intentions and family consent for cadaveric donation.

CHARACTERISTICS OF INDIVIDUALS WILLING TO BE DONORS

Much of the effort to increase the potential donor pool has focused on bolstering public attitudes toward organ donation and the behavioral actions of documenting donation intentions and informing family members of those intentions. Despite apparent public support for cadaveric organ donation,³ few individuals sign and carry organ donor cards, estimated in one study at 23% of the U.S. population.⁴ Studies examining socio-demographic characteristics of individuals with a positive view of organ donation have suggested that women, whites, persons of higher socioeconomic status, greater education and younger age are more likely to report favorable attitudes toward organ donation and more likely to sign donor cards.⁵⁻¹⁰ These studies, however, have tended to confound race and socioeconomic status. It is important to note that the presence of documentation of intention to donate is almost always honored by family and health professionals, a finding that underscores the need for innovative interventions to spur that intention and documentation.

CHARACTERISTICS OF FAMILIES WHO CONSENT TO DONATION

Families of potential donors are central to the donation request process, however, little is known about how families make donation decisions. As with attitudes toward donation and donor card signing, families who consent to donate are more likely to be white, have favorable attitudes toward donation, and be aware that their deceased family member had signed a donor card or was pro-donation.¹¹⁻¹³ Several studies, as well as anecdotal reports, have suggested that African-

Abbreviations Used:

TTM	Transtheoretical Model
UNOS	United Network for Organ Sharing

American and Latino families are more likely to refuse requests for donations than white families.¹⁴ This trend is troubling because African-Americans are disproportionately on the UNOS waiting list due primarily to a higher incidence of end-stage renal disease.¹⁵

STAGES OF CHANGE AND ORGAN DONATION

Understanding the sociodemographic factors associated with organ donation is helpful but not sufficient to advise interventions that move populations to the desired actions. To encourage individuals to become organ donors or consent to donate the organs of a loved one, we need to understand the five stages of readiness that people progress through when making important decisions: precontemplation, contemplation, preparation, action and maintenance.

In the precontemplation stage, individuals do not intend to take action (e.g., document donation intent), even if that action could be lifesaving. These individuals are not ready for interventions that require immediate action. Studies across more than a dozen of the most serious health and mental health behaviors have shown that people in this stage underestimate the benefits of changing to a healthier behavior and overestimate the difficulties of implementation.² Furthermore, precontemplators are typically not conscious of their erroneous evaluations of the costs and benefits of changing. Without interventions matched to their needs, these individuals are likely to remain stuck at this stage.

In the contemplation stage, individuals are considering action. They are more aware of the pros of change than are individuals in the precontemplation stage. They are also more aware of the cons, however, and the balance of their opinion is delicately poised, leading to a tendency to substitute thought for action.

The ideal group for action-oriented interventions is in the preparation stage. They are convinced that the pros outweigh the cons, and their most serious concern is with learning to take the most effective course of action to increase the likelihood of a successful decision. Individuals in the action stage have recently changed their behavior. They continue to believe the pros of their decisions outweigh the cons and, in the case of donation intentions, feel stronger in their determination to continue that choice. Finally, individuals in the maintenance stage are successful at continuing to renew their decisions when appropriate.

One of the assumptions of the Transtheoretical Model is that people can apply a common set of change processes or methods across a broad range of behaviors. Further, these change processes have been found to have differential effectiveness depending on level of readiness for the behavior change. For example, individuals in precontemplation for donating a loved one's organs need to be educated about the benefits of donation and offered interventions that decrease their fears of the process, while individuals in action need strategies to maximize cues to help them complete the donation process. A key implication of this model is that interventions to increase donation intentions and family consent rates need to be matched to each individual's stage of readiness. Evaluating this premise in the family consent scenario, we can see that offering families the option to donate before they fully understand that their loved one is dead is a mistake that leads many families to refuse consent. Offering the "right" intervention at the "wrong" time is unlikely to produce the desired behaviors. This hypothesis is sup-

ported by research on situational factors and family consent that have found increased consent rates when families have a thorough understanding of brain death and the request for consent is clearly differentiated from the explanation of brain death.^{16,17}

*As of June 30, 1998,
there were more than
56,000 patients on the
UNOS waiting list.*



STAGE-BASED INTERVENTIONS FOR ORGAN DONATION

Several projects applying the transtheoretical model to increasing donation intention and family consent rates are underway at the University of Rhode Island. Measures of readiness, pros and cons, and confidence to become an organ donor are being developed with college students and adults. These measures when linked to stage-matched interventions will help guide individuals as well as community campaigns to increase donation intention.

This approach is also being used to increase family consent in collaborative projects with organ procurement agencies. Again, measures of readiness, pros and cons, and confidence for consenting to organ donation are being developed. Planned interventions for increasing family consent rates include a stage-based counseling curriculum for organ procurement coordinators as well as stage-based materials for family

members.¹⁸ A similar program including a computer expert system intervention to deliver training in stage-based assessment and counseling for family consent is being developed for use with physicians and nurses.

The organ supply may never match the ever-growing demand, but there is room for growth in donation intention and family consent rates. To spur that growth, we need to understand more about how people make donation decisions for themselves and others. Twenty years of research on health behavior change and decision making suggest that a readiness approach offers significant advantages in the effort to increase organ donation. With this approach we can develop interventions appropriate for all populations, tailored to each person's level of readiness for organ donation.

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The Humerus Moment
- Graça Soares, MD



THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

Autobullectomy: Spontaneous Improvements in Pulmonary Function and Symptoms in a Patient with Bullous Emphysema

Alan R. Muster, MD, Sharon Rounds, MD, and Michael Cutaia, MD

Surgical bullectomy has been used in the past for the treatment of limited bullous emphysema.¹ During the last decade, surgical bullectomy and volume reduction surgery have been rediscovered for the treatment of severe COPD. Although the literature reports improvement in PFTs and symptoms, the long term effectiveness of these treatments remains unclear.^{2,3}

The following case report demonstrates a spontaneous event, resulting in autobullectomy with improvement in PFTs and symptoms. About one year after the event, PFTs returned to pre-event values, and the patient's clinical status also deteriorated.

CASE REPORT

A 44 year old white male has been followed in the Pulmonary Clinic for severe bullous emphysema since 1984. In early 1992, it was noted that his PFT's had dramatically improved in comparison with a prior study in 1989 (Table 1). Specifically, the forced vital capacity (FVC) had increased by 710 ml and the forced expiratory volume in one second (FEV₁) had increased by 530 ml (nearly 50%) over the three-year period, while the residual volume (RV) had decreased by a similar amount. At the time, the patient stated that his symptoms of dyspnea on exertion and shortness of breath had also improved. No dramatic medical events were known to have occurred, and no major changes in therapy had been undertaken during that time.

A review of the patient's chest radiographs revealed severe bullous emphysema of the upper lung fields bilaterally (Figure 1), present since 1984. Between May and December of 1991, the chest radiograph showed a significant decrease in the bullous disease of the left upper lung (Figure 2, Panel A). Chest CT scan showed herniation of a

Abbreviations Used:

COPD	chronic obstructive pulmonary disease
FEV ₁	forced expiratory volume in one second
FVC	forced vital capacity
PFTs	pulmonary function tests
RV	residual volume

right-sided bullus across the mediastinum and into the left hemithorax (Figure 2, Panel B).

Followup PFTs one year later demonstrated return of FEV₁, FVC and RV to their previous values, and these have subsequently remained stable (Table 1). Clinical symptoms also worsened, with increased dyspnea on exertion.

DISCUSSION

Volume reduction surgery and bullectomy have been reported to improve pulmonary mechanics and shortness of breath.^{1,4-6} Nonsurgical lung volume reduction may also improve pulmonary function. For example, three patients with severe pulmonary infections and one who had undergone radiation therapy for lung cancer were reported in an abstract in *Chest* in 1995.⁷ These patients, who all had pre-existing severe COPD, experienced increases in FEV₁ ranging from 50 to 100%. Goodman and Lakshminarayan recently published a series of chest radiographs documenting the occurrence of an inflammatory autobullectomy.⁸

Our patient did not recall an "event" such as pneumonia or radiation therapy during the time his chest radiograph changed, but was incidentally noted to have improved PFTs. On questioning at the time, the patient stated he was less short of breath and able to do more daily activities. His chest radiographs demonstrated dramatic decrease in the

DATE	FEV1	FVC	TLC	RV	FEV1%	RV/TLC
11/22/89	1.09	2.91	6.85	3.75	37%	55%
4/17/92	1.62	3.62	6.92	3.21	45%	46%
3/12/93	0.8	2.15	7.08	4.39	37%	62%
4/18/94	1.06	2.66	7.01	4.12	40%	59%

Table 1: Pulmonary Function Tests for the patient before and after the autobullectomy(1991)



Figure 1. Chest radiograph of the patient in May, 1991, revealing severe bullous disease of the upper lung zones bilaterally.



Figure 2, Panel A. Chest radiograph of the patient in December, 1991, revealing a decrease in the amount of bullous disease in the left upper lung field.



Figure 2, Panel B. Chest CT scan of the patient in March, 1994 which shows the right sided bullae herniating into the left hemithorax.

bullous disease on the left, that coincided temporally with the improvement in PFT's and functional status. Thus, this patient experienced a spontaneous "autobullectomy."

The effects of surgical bullectomy in patients with COPD vary among different clinical series.¹ The degree of physiologic improvement in pulmonary function and the duration of the improvement in patient functional status is difficult to predict. Followup of these patients is often of short duration, leaving gaps in the documentation of the duration of reported physiologic and subjective benefit. In general, there is initial improvement, followed by a gradual

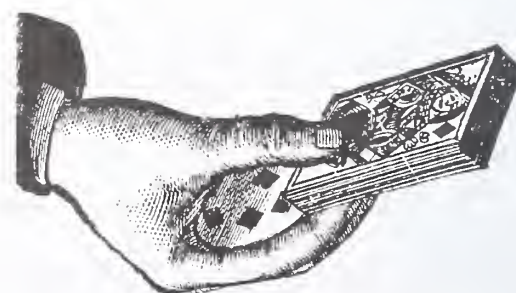
return of symptoms and FEV₁ to preoperative levels in most patients, related to progression of disease and/or continued smoking.^{6,9} Our patient demonstrated a reversal of the beneficial effects of autobullectomy with repeat PFTs 11 months later. The PFTs at that time were actually worse than they had been before the spontaneous autobullectomy, but later stabilized at values close to the pre-autobullectomy level.

Although it is hard to relate the events described in this report to the results of surgical procedures to treat COPD, the return of PFTs and clinical symptoms to the pre-event state raises the concern that this may also occur in patients treated by bullectomy or volume reduction. This case suggests that randomized, multicenter trials with long-term followup are needed to objectively evaluate the long-term results of volume reduction surgery as a form of treatment for severe COPD.¹⁰

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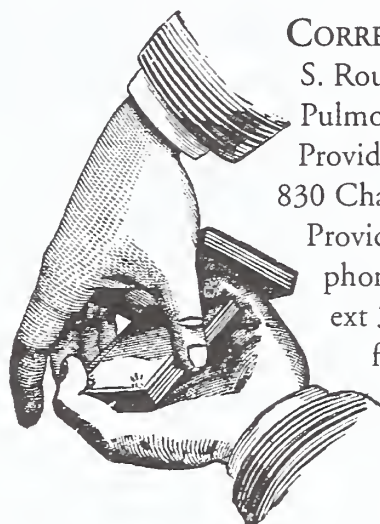
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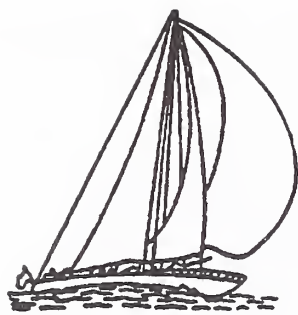
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Health Care Quality Improvement in Rhode Island: Congestive Heart Failure

Congestive heart failure (CHF) is a common chronic disease in the elderly with serious morbidity and mortality consequences.¹ The prevalence of CHF is likely to increase as the population ages and survival rates improve for individuals with cardiovascular diseases. CHF is the leading cause of hospitalization among Medicare beneficiaries, nationally and in Rhode Island. Because of the increasing incidence, high mortality rate, high costs of care, and impaired quality of life associated with CHF, this condition has become a priority area for the Health Care Financing Administration (HCFA) and the Health Care Quality Improvement Program. Many states have already conducted projects on CHF. RIQP is currently planning two projects on CHF. The first project takes place in the ambulatory setting; the second project, in the hospital setting. This month's column will serve as an update on these projects.

There is increasing evidence that many of the consequences of CHF are preventable by following established guidelines of care. The Agency for Health Care Policy and Research² and the American College of Cardiology/American Heart Association³ have recently published such guidelines. Appropriate use of ACE inhibitors reduces mortality and disability due to CHF. Ejection fraction measurement identifies candidates for this therapy. New models of care delivery have been demonstrated to be efficient in the prevention of common complications.⁴ Risk factors for hospitalization can be identified¹ and intervention can prevent readmissions for CHF via a multidisciplinary team approach to case management.

ACE INHIBITOR USE

Despite the well-established evidence base that ACE inhibitors reduce mortality and improve functional status in CHF, ACE inhibitor utilization in CHF remains suboptimal.^{5,6} In the early 1990s, approximately 30% of appropriate candidates were actually receiving this therapy. Practitioners perceived that they were prescribing these drugs somewhat more frequently; with cardiologists reporting more use than internists, who reported more use than

Abbreviations Used:

ACE	Angiotensin-converting enzyme
CHF	congestive heart failure
CME	Continuing Medical Education
HCFA	Health Care Financing Administration
MCO	managed care organization
PRO	Peer Review Organization
RIQP	Rhode Island Quality Partners

General Practitioners and Family Practitioners. This is important since the vast majority of patients with CHF are being treated by non-cardiologists. More objective evaluation of practice patterns reveals that less than 20% of initial prescriptions for CHF include ACEIs, with cardiologists prescribing them more frequently. More physicians use diuretics and digitalis glycosides than ACEIs.

ACE inhibitor utilization in CHF was the subject of a recent multi-state, hospital-based PRO study.⁷ More than 600 charts with CHF as a discharge diagnosis were abstracted in each of the 10 most populous states. At the time of admission, 35% of patients were taking ACE inhibitors. These agents were prescribed at discharge in 55% of patients. Ejection fractions were documented in 59% of the records. Seventy-three percent (73%) of ideal candidates were discharged on ACE inhibitors. Ideal candidates are a subset of patients without any contraindications (relative or absolute) to ACE inhibitor use.

HOSPITAL READMISSIONS

The national 30-day readmission rate for CHF is 23% and the 6-month readmission rate is 35%.⁸ Over half of readmissions have been judged to be potentially preventable and risk factors for preventable readmissions have been identified. These include non-compliance with medication, non-compliance with diet, inadequate discharge planning, inadequate follow-up, failed social support system, and failure to seek medical attention promptly when symptoms recur.⁹

A recent series of investigations has demonstrated that: 1. risk factors for readmission in CHF can be identified; 2. these risk factors can be modified using a multidisciplinary team approach to patient care; and 3. risk factor modification using this method prevents readmissions for CHF. The treatment strategy in this intervention was designed to minimize medication non-compliance and errors, dietary indiscretion, and the impact of inadequate discharge planning and follow-up.^{4,9,10}

CHF PROJECT IN AMBULATORY SETTING

RIQP is working with a hospital and a managed care organization (MCO) on a case management project in CHF. This project will focus on patients discharged from the hospital with a diagnosis of CHF. The interventions are designed to prevent premature death, rehospitalization, and to improve quality of life. Process measures will focus on ACE inhibitor utilization, ejection fraction measurement, and issues in patient education. Outcome measures will include mortality, hospitalizations, quality of life, and other components of health care utilization. The core intervention for this project is a multidisciplinary team, led by a cardiologist and case manager, that will advise primary care physicians on implementing best practices in CHF, and help manage the complex sets of services often associated with these practices. A software package is being developed to facilitate communication among the team members and the primary care physicians.

CHF PROJECT IN HOSPITAL SETTING

RIQP recently surveyed the hospitals and MCOs in Rhode Island and found CHF to be the overwhelming favorite for a hospital-based project. We are happy to announce that all ten acute care hospitals and multiple MCOs have agreed to collaborate. The project will focus on ACE inhibitor utilization, ejection fraction measurement, and important components of patient education. The measurement tool was developed in Connecticut and is being used nationally. The baseline measurement will include hospitalizations for CHF from April 1997 through March 1998. Analysis will be conducted later this year. In addition to interventions designed by our collaborators, RIQP and the Brown University School of Medicine will offer Continuing Medical Education (CME) activities through the Series on Health Care Quality Improvement in Rhode Island.

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Edward Westrick, MD, MS, is the Principal Clinical Coordinator of Rhode Island Quality Partners. He is a member of the clinical faculty of Brown University School of Medicine and the Active Medical Staff of Roger Williams Medical Center. He is currently a PhD candidate at the University of Rhode Island in Pharmacoepidemiology and Pharmacoeconomics.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Health by Numbers



Rhode Island Department of Health
Patricia A. Nolan, MD, MPH, Director of Health

Edited by Jay S. Buechner, PhD, and William J. Walter, Jr., PhD

Enrollment Trends in Medicare Managed Care Plans

Jay S. Buechner, PhD

Between 1990 and 1996, there was a substantial increase in the number of Rhode Islanders who were members of health maintenance organizations (HMOs), by the latter year, the market share of HMOs had reached 35% of persons under age 65 who had health insurance.¹

Among persons covered by the federal Medicare program, most of whom are age 65 and older, the option of enrolling in an HMO rather than the traditional fee-for-service system has been available since as early as 1985. However, until recently, the enrollment of Medicare beneficiaries in HMOs has grown much more slowly than among younger persons, both in Rhode Island and nationally. Now the growth in HMO enrollment is beginning to accelerate in this population much as it did among younger persons.

Medicare allows HMOs to offer two main types of managed care plans: risk-contracting plans and cost-contracting plans. Under risk-contracting plans, HMOs receive a monthly payment for each member, the amount being determined from the local cost experience in the fee-for-service system, and are responsible for providing all covered services needed by the member. If the cost of services provided differs from the payment, the HMO keeps any unexpended amount or bears the

Abbreviations Used:

BBA	Balanced Budget Amendment of 1997
HCFA	Health Care Financing Administration
HMO	health maintenance organization

loss for costs over the payment received. Under cost-contracting plans, HMOs return some or all unexpended amounts or are reimbursed for some or all costs of services that exceed the payment received. In recent years, the growth in Medicare HMO enrollment has been predominantly in risk-contracting plans.

Methods

Data on total Medicare enrollment, total enrollment in HMOs, and enrollment in specific health plans for each county in the United States are produced quarterly (March, June, September, December) by the Health Care Financing Administration (HCFA). These summary data are published on the HCFA website (www.hcfa.gov), and individual plans are identified and are characterized as risk-contracting or cost-contracting.

Rhode Island statewide data were aggregated from county data, and national summary data through December 1997 are available from published reports.²

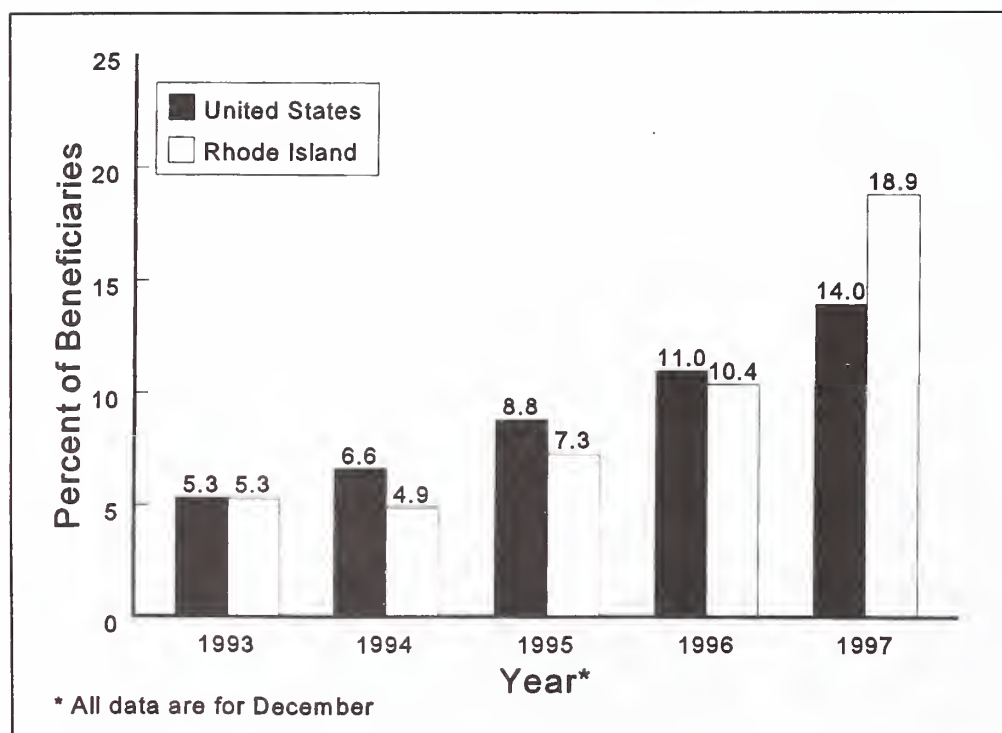


Figure 1. Enrollment in Medicare Risk-Contracting Plans, United States and Rhode Island, 1993 - 1997.

Results

Between December 1993 and March 1998, enrollment in Rhode Island's Medicare HMOs more than tripled, from 12,654 persons to 39,202 persons. In 1993, risk-contracting plans held the large majority of managed care enrollees (71%); by 1998, they totally dominated cost-contracting plans with a 98% share of managed care enrollees. The growth of enrollment in Medicare risk plans in Rhode Island as a percentage of total Medicare enrollment surpassed the growth rate nationally over the four-year period from December 1993 to Decem-

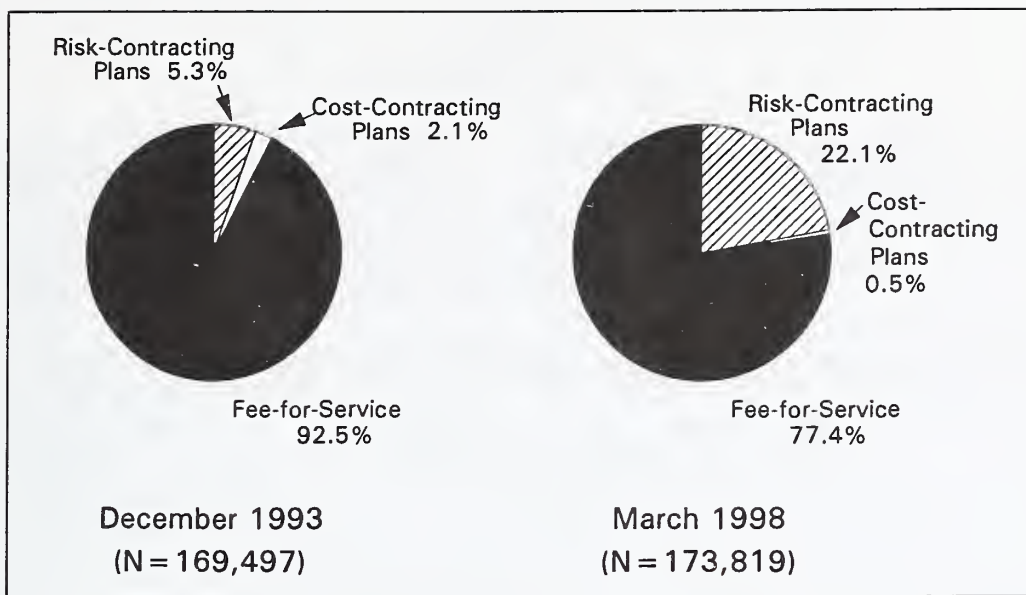


Figure 2. Medicare Enrollment, by Type of Plan, Rhode Island, December 1993 and March 1998.

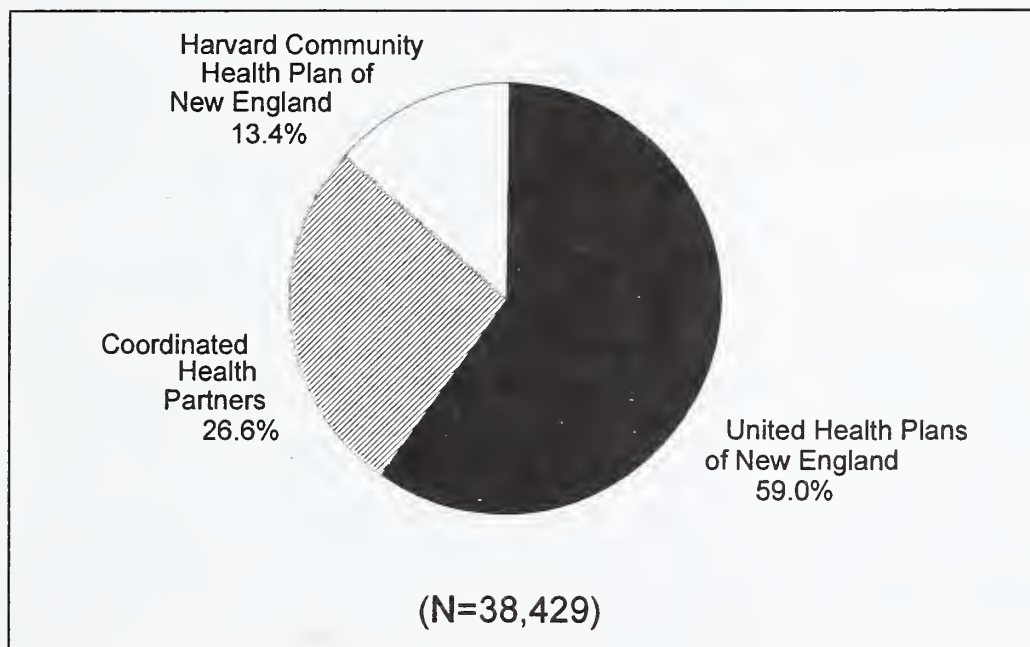


Figure 3. Enrollment in Medicare Risk-Contracting Plans, by Plan, Rhode Island, March 1998.

ber 1997, with an especially large increase in enrollment between 1996 and 1997 in the state. (Figure 1). By March 1998, risk plans had enrolled over 22% of Medicare eligibles in Rhode Island. (Figure 2.) Over the three-month period from December 1997 to March 1998, risk plans added an average of 1% of the state's Medicare eligibles to their enrollment during each month.

The growth in enrollment in Medicare risk plans in Rhode Island has been accompanied by an increased number of the state's HMOs offering such plans. In 1993, only one HMO offered a Medicare risk plan; one other offered a Medicare cost-contracting plan. In 1998, three HMOs offer Medicare risk plans, one offering two such plans. One of the HMOs offering a risk plan continues to offer its cost-contracting plan also.

The majority of enrollees (59%) in Medicare risk plans belong to United Health Plans of New England, which offered the first risk plan in the state. (Figure 3.) The second largest market share is held by Coordinated Health Partners, which has only operated its risk plan since 1997, followed by Harvard Community Health Plan of New England.

Discussion

The growth in managed care enrollment among working-age persons has been driven in great part by the cost-control pressures felt by employers, who are most often the purchasers of health care coverage for persons in this age group.

However, the growth in managed care enrollment among Medicare eligibles has been the result of the voluntary choice of these plans over the traditional fee-for-service system. For the most part, these plans have been made attractive because the payment formula used by Medicare has been generous enough to allow the HMOs to enhance the benefits covered by their plans, including, in some cases, coverage for the deductibles and/or co-payments that fall on the patient in the fee-for-service system.

The Balanced Budget Amendment of 1997 (BBA) makes changes in the Medicare managed care program, now called Medicare Plus Choice or Medicare Part C, that may affect the growth rate of enrollment in risk-contracting plans. Most significantly, BBA extends the range of health plan options within Medicare to include preferred provider organizations, provider-sponsored organizations, private fee-for-service plans, and medical savings account plans. Also significant is the introduction of a phased-in system of calculating monthly capitation rates that will reduce the large differential between the low rates in most rural counties and the

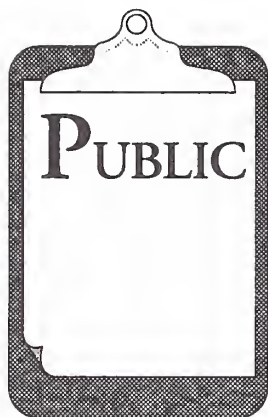
high rates in most urban counties. The BBA also mandates the introduction as of January 2000 of a system of risk adjustment to capitation rates that is expected to reduce the financial advantage accruing to plans with healthier enrollees.

These changes are likely to have a substantial impact during the next few years on the number and type of plans available to Medicare beneficiaries and in their patterns of enrollment in these expanded health plan options.

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Calcium in the Diet of Rhode Island's WIC Preschoolers

Becky Bessette, MS, RD

Rhode Island's Nutrition Program for Women, Infants, and Children (WIC Program) provides nutrition counseling, free nutritious foods, and information about other programs to 24,000 eligible women, infants, and children up to age 5 with nutritional risks. Among the 13,000+ preschool children in the RI WIC Program, over 4,700 (36%) have diets low in calcium.

WHY ARE WE CONCERNED ABOUT CALCIUM INTAKE AMONG PRE-SCHOOLERS?

Development of Eating Patterns:

Identifying dietary deficiencies early gives parents an opportunity to modify their family's eating habits, while providing healthful diets to their new infant and preschoolers. Early education and access to nutritious foods help develop and reinforce good eating habits. Programs like WIC and Head Start reinforce the practices and information necessary in the development of good eating habits for children and their families.

Bone Growth and Osteoporosis Prevention:

Bone development starts at birth and continues into young

adulthood. Adequate intake of calcium (and Vitamin D) in this period of rapid growth is essential for optimum bone development.

Lead Poisoning Prevention:

The consumption of adequate calcium slows absorption of lead by the body. Other dietary preventives include adequate iron, snacks, and avoiding fatty foods.

WHY ARE WIC PRESCHOOLERS AT SUCH RISK?

Income status plays a role:

Low calcium diets are more common among low-income children, in part because of restricted food budgets, lack of nutrition education, and barriers to helpful programs.

Infancy to Toddler to Preschooler/Time of Transition:

The early years of life encompass many dietary transitions for young children and their families. During infancy, breast milk and iron-fortified infant formula are key components of diets, providing adequate amounts of calcium for accelerated growth in the first year of life. The addition of solid foods during months 6-12 begins the transition to a toddler's diet. The variety of foods offered, feeding patterns, and social dynamics during meal time may affect calcium consumption in this time of transition.

Age as a Factor:

Among preschoolers in the Rhode Island WIC Program, the risk of inadequate calcium intake (less than 2-3 cups of milk per day or equivalent, depending on the child's age) appears to increase with the age of the child. A four year old has twice the risk of low calcium consumption as a two year old (Table 1).

Ethnicity / Race as a Factor:

Among preschoolers in the Rhode Island WIC Program, Asian, Native American, and African American children are more likely than others to be at risk of low calcium intake. One half of the Asian children have diets low in calcium (Table 2). Factors contributing to the low calcium intake of preschoolers in these groups may include lactose intolerance (which is more prevalent among people of Mediterranean

Table 1.
Percentage of preschoolers in the Rhode Island WIC Program with insufficient calcium in the diet, by age

Age	Percentage with insufficient calcium
1	11%
2	28%
3	46%
4	60%

Table 2.
Percentage of preschoolers in the Rhode Island WIC Program with insufficient calcium in the diet, by race and ethnicity

	Percent	(N)
All	36%	(13,296)
White, non-Hispanic	33%	(6,366)
Hispanic	33%	(4,401)
African American, non-Hispanic	41%	(1,929)
Asian	49%	(540)
Native American	43%	(60)

Table 3.
Foods high in calcium

Dairy Products	Fish and Beans	Vegetables	Other Foods
Milk*	Salmon	Broccoli	Dark Molasses
Buttermilk*	Ocean Perch	Collard Greens	Cornbread
Powdered Milk*	Mackerel	Kale	Orange juice+Ca*
Lactaid Milk*	Sardines with bones	Spinach	
Yogurt*	Tofu*	Turnip Greens	
Ice Cream			
Cottage Cheese			
Ricotta Cheese*			
Pudding*			

* Excellent source of calcium

origin, Asians, Native Americans, and African Americans) and individual and cultural preferences.

COMMENTS FROM THE FIELD

Anecdotal reports from nutritionists in Rhode Island's WIC Program have associated low calcium consumption in the diets of preschoolers with a number of factors:

- Delayed transition from baby bottle to cup, resulting in refusal to drink milk from cups
- Parents' lack of knowledge about the need for calcium sources in the diet
- Excessive intake of juices, fruit punches, and soda, displacing milk in the diet
- Limiting milk intake because of "lactose intolerance" (although frequently a temporary intolerance induced by infectious diarrhea or medications)
- Cultural food habits that regularly preclude the use of dairy foods, but do not substitute sufficient quantities of other calcium-rich foods

RESOURCES AND SUGGESTIONS FOR HEALTH CARE PROVIDERS

KIDS NET:

KIDS NET is a public health computerized information management system that tracks children's public health preventive services from eight public health data bases, including information on the nutritional risks of children enrolled in the WIC Program. Using KIDS NET, authorized users may obtain this information and other pertinent information, such as weight, stature, and the results of occasional tests. (For more information call 1-888-880-KNET.)

Dietary Guidance:

Calcium sources are found in a variety of food groups (Table 3). The Recommended Daily Dietary Allowance (1989) for calcium is 800 mg. for children from one to six years of age, the equivalent of 2-3 cups of milk in the context of a diet which supplies small amounts of calcium from other food groups. Educating parents about a child's diet should be based on a holistic review of the child's food habits. Parents should be encouraged to feed the child according to

the Dietary Guidelines for Americans or the USDA's Food Guide Pyramid, both of which focus on servings from major food groups. The Rhode Island WIC Program has modified the USDA's Food Guide Pyramid, adjusting the serving sizes based on a child's age.

Cultural sensitivity and literacy level of education and materials:

Dietary guidance must be individualized and culturally appropriate. Recognizing that ethnic groups may consume "non-traditional" sources of calcium (tofu,

vegetables, fish), or that lactose intolerance may be a concern for some, counseling and education should reflect these differences. Dietary information should include foods from various cultures. The Rhode Island WIC Program has nutrition education materials written in 10 languages (6th grade level). Samples are available by calling Becky Bessette, Rhode Island Department of Health WIC Program, at (401) 222-4604.

Refer families to nutrition programs in their community:

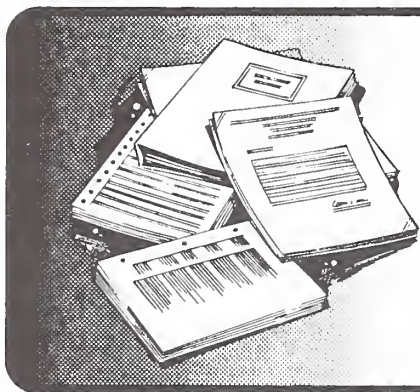
The WIC Program, Head Start, and the Expanded Food and Nutrition Education Program are examples of free nutrition programs available to income eligible families.

- WIC: provides free nutritious foods, nutrition education, and referrals to other needed services throughout RI to income eligible pregnant and breastfeeding women, new mothers, infants and children (up to age 5) who have a nutritional / medical risk. Call the Rhode Island Department of Health at 1-800-942-7434 for referral materials and additional information.
- Head Start: Provides classroom meals, nutrition education for both parents and children, and nutrition assessments and counseling for income eligible preschoolers. Call your local school system to find the Head Start Program serving your community.
- Expanded Food and Nutrition Education Program: Helps families learn the basics about nutrition, food budgeting, food safety, and menu planning. Classes are held in the community or in homes. Call the URI Cooperative Extension Office at 277-5270 for information.

The Nutrition Hotline:

Staffed by a licensed nutritionist, the Nutrition Hotline provides consumers, educators and health care professionals with nutrition information, resources and brochures. Call the Rhode Island Department of Health at 1-800-624-2700 on Monday, Wednesday or Friday between 9 am and 1 pm for answers to your nutrition questions.

Becky Bessette, MS, RD, is the Rhode Island State WIC Nutrition Coordinator, Rhode Island Department of Health.



CLINICAL TRIALS DIRECTORY

Medicine & Health/ Rhode Island is pleased to launch this Directory. In Rhode Island, many researchers—hospital-based and community-based—are conducting clinical trials; but the channels of communication are not optimal. We intend this Directory of Clinical Trials to serve as an information clearinghouse for ongoing trials in the state. If you would like to list a trial, please contact:
Joan Retsinas
Managing Editor
phone/fax: (401) 272-0422
e-mail: JRetsinas@aol.com.

A Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging, Study for the Safety, Tolerability and Efficacy of S1B-1508Y in Parkinson Disease Patients who are Requiring but Not Receiving Dopaminergic Therapy

Sponsor: S1B1A Neurosciences and the Parkinson Study Group

Purpose: Joseph Friedman, MD, is conducting this trial to treat patients with early Parkinson's Disease. Patients will be treated with varying doses of a nicotinic agonist looking at both symptomatic motor effect and memory enhancement.

Patients Recruited: People with Parkinson's Disease not receiving Dopaminergic drugs. MMSE must be >24. May be on Eldepryl. No agonists, amantadine, antidepressants, or neuroleptics.

Intervention: varying doses of S1B-1508Y vs. placebo

Duration of study: 5 weeks

Phase: IIa

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

A Multi-Center, Placebo-Controlled Trial of Melatonin for Sleep Disturbance in Alzheimer's Disease

Sponsor: Alzheimer's Disease Cooperative Study

Purpose: Brian Ott, MD, is conducting this trial to treat Alzheimer's Disease patients who experience sleep disturbances associated with Alzheimer's Disease. Two doses of melatonin will be used to treat sleep disturbances in order to lessen the burden on caregivers and family members.

Patients Recruited: Anyone 55 years or older with a diagnosis of probable Alzheimer's Disease experiencing sleep disturbances.

Intervention: Two doses of Melatonin vs. placebo

Duration of study: 12 weeks

Phase: III

Site: Alzheimer's Disease & Memory Disorder Clinic, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Michael Pimental, MA, phone (401) 729-3752

Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Trial of Intracerebroventricular Recombinant-Methionyl

Human Glial Cell Line-Derived Neurotrophin Factor (r-met HuGDNF) for the Treatment of Patients with Idiopathic Parkinson's Disease

Sponsor: Amgen, Inc., and Medtronic, Inc.

Purpose: Joseph Friedman, MD, is conducting this trial which involves neurosurgical placement of a reservoir to allow intracerebroventricular administration of the study material. Patient will receive study material injection into the reservoir once a month for an indefinite length of time.

Patients Recruited: Patients must have Parkinson's Disease with bilateral symptoms, be between 35 and 70 years old, have a response to levodopa and/or agonist, no prior surgery for P.D., and must have significant difference between "on" and "off" periods.

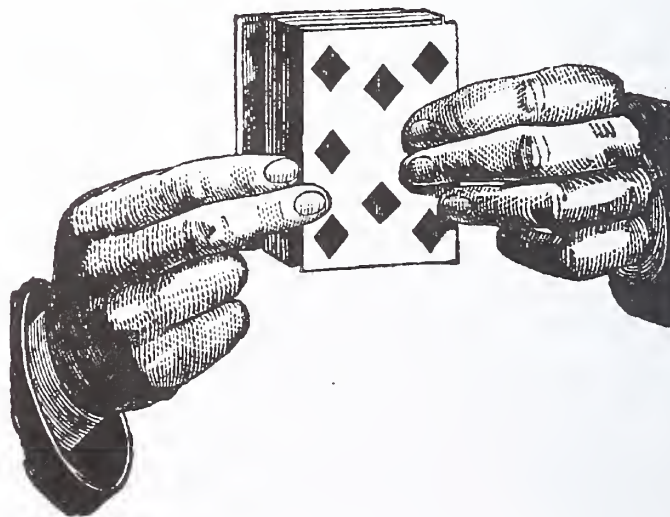
Intervention: various doses of r-met HuGDNF vs. placebo

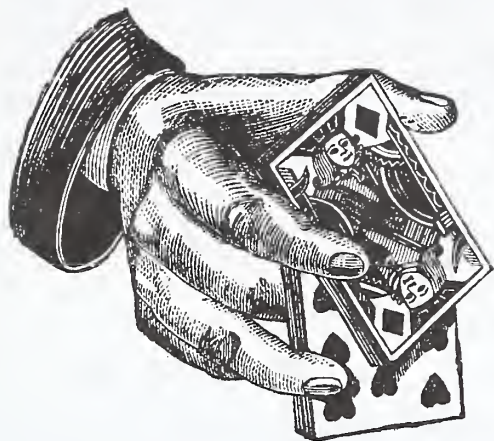
Duration of study: 6 months to indefinite

Phase: I/II

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750





Earlier vs. Later Levodopa in Parkinson's Disease (ELLDOPA)

Sponsor: NIH and the Parkinson Study Group

Purpose: Joseph Friedman, MD, is conducting this trial to compare the effect of early or late treatment of Parkinson's Disease with L-Dopa to answer the question of whether L-Dopa slows or hastens the progression of Parkinson's Disease.

Patients Recruited: Patients must be 30 years or older, must be diagnosed with Parkinson's Disease within the last 2 years. No eldepryl, L-DOPA, amantadine, anticholinergics, antihistamines, antidepressants, or benzodiazepines for previous 30 days.

Intervention: varying doses of Carbidopa/Levodopa vs. placebo

Duration of study: 9 months

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

For HIV Infection: DMP 266-006: A Phase III, Multicenter, Randomized, Open-Label Study to Compare Antiretroviral Activity and Tolerability of Three Different Combination Regimens in HIV-Infected Patients

Sponsor: DuPont Pharmaceuticals

Purpose: This trial evaluates three highly effective combinations (DMP266 + Indinavir; DMP266 + Zidovueine + Lamivudine; Indinavir + Zidovudine + Lamivudine), including a promising drug called DMP266 (efavirenz, Sustiva). Karen Tashima, MD, is the principal investigator.

Patients Recruited: HIV-infected adults who have taken few or no antiretroviral medications.

Intervention: three combinations of drugs (DMP266 + Indinavir; DMP266 + Zidovueine + Lamivudine; Indinavir + Zidovudine + Lamivudine), including DMP266 (efavirenz, Sustiva).

Compensation: Patients receive compensation.

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Timothy Bose, phone: (401) 793-4971

For HIV Infection: An Open-Label, Two-Center Trial to Evaluate the Efficacy and Safety of Quadruple Chemotherapy (Epidur, 1592U89, and 141W94 with Indinavir) in Subjects Newly Infected with HIV-1

Purpose: Conducted with the Aaron Diamond AIDS Research Center, this trial is for patients who are in the seroconversion period when circulating virus is at very high levels. The potential benefit of treating with four antiretroviral medications at this stage of HIV infection will be investigated. Karen Tashima, MD, is the principal investigator.

Patients Recruited: Patients in the seroconversion period (prior to the development of HIV antibodies)

Intervention: Epidur, 1592U89, and 141W94 with Indinavir

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Joan Gormley, RN, phone: (401) 793-4398

HIV: Expanded Access Programs

Intervention: Efavirenz (a non-nucleoside reverse transcriptase inhibitor) and abacavir (nucleoside reverse transcriptase inhibitor) are available in expanded access programs. Karen Tashima, MD, is the principal investigator.

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Joan Gormley, RN, phone: (401) 793-4398

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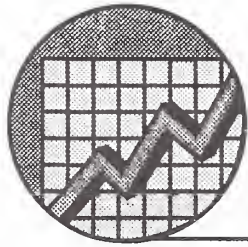
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Rhode Island does not have a procedure for certification of specialization by lawyers.



Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	March 1998	12 Months Ending with March 1998	
	Number	Number	Rates
Live Births	1,240	13,446	13.6*
Deaths	875	9,942	10.0*
Infant Deaths	(10)	(92)	6.8#
Neonatal deaths	(6)	(74)	5.5#
Marriages	301	7,825	7.9*
Divorces	235	3,243	3.3*
Induced Terminations	375	5,276	392.4#
Spontaneous Fetal Deaths	83	942	70.1#
Under 20 weeks gestation	(73)	(883)	65.7#
20+ weeks gestation	(10)	(59)	4.4#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	September 1997	12 Months Ending with September 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	200	3,377	341.0	3,894.0
Malignant Neoplasms	203	2,477	250.1	6,915.0
Cerebrovascular Diseases	64	699	70.6	847.5
Injuries (Accident/Suicide/Homicide)	20	333	33.6	6,461.0***
COPD	30	445	44.9	290.0**

**Excludes one death of unknown age

***Excludes two deaths of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

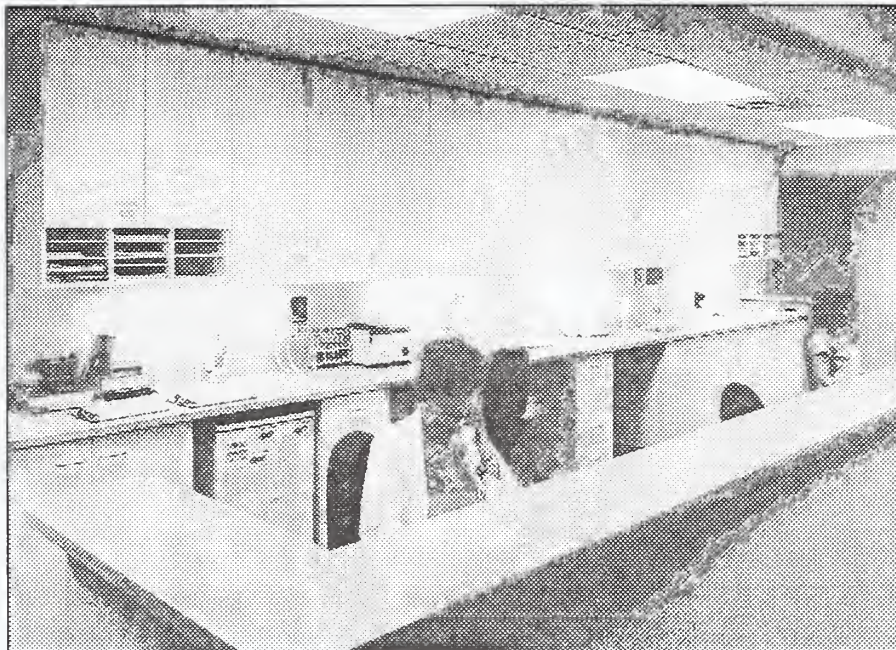
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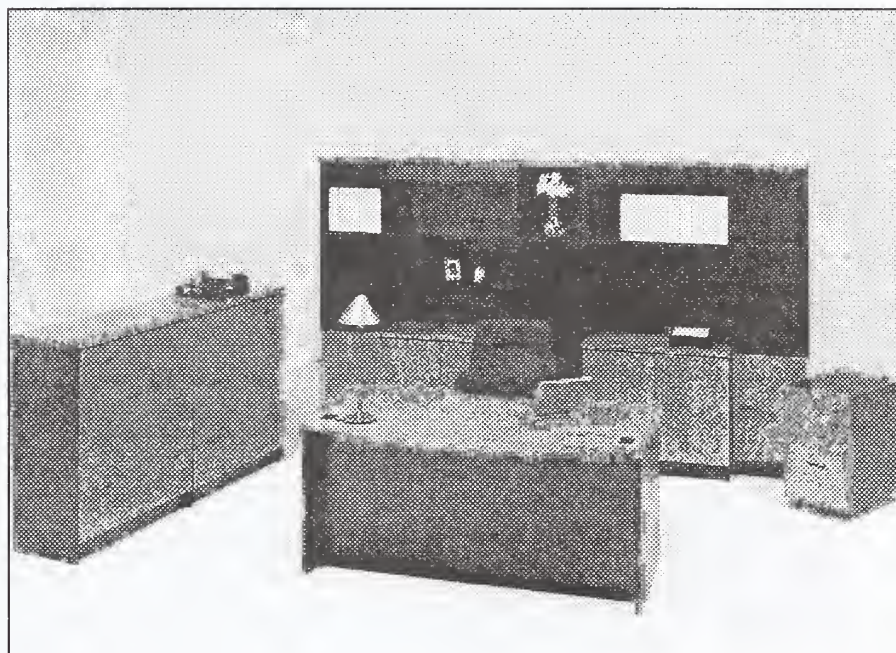
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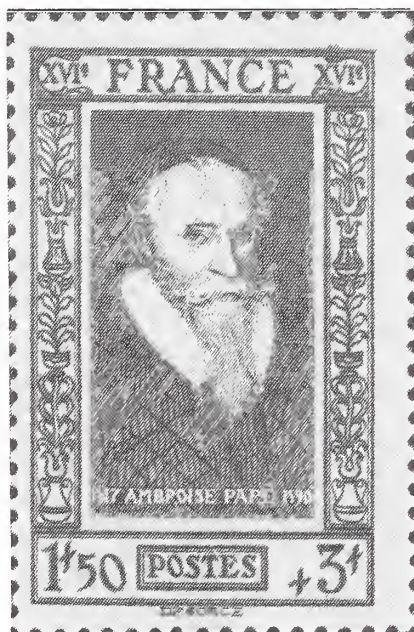
☞ Semipostal Stamps ☞

A semipostal stamp has two fees. The first and higher fee represents the price for the postage; the lower fee represents a mandated contribution to a specific charity. Many of the international issuing authorities issue semipostal stamps.

Among the more medically interesting semipostals are two from France. [France, 1943, #B163] pictures Amboise Paré, a famous French surgeon. The postage was 1.50 francs and the mandated donation was 3 francs for a charity (in this instance, the Recreation Fund of the employees of the Post, Telephone and Telegraph).

[France, 1938, B59] depicts Louis Pasteur (1822-1895), a famous professor of chemistry and the father of

the germ theory of disease. The portion for postage on the Pasteur semipostal is 1.75 francs and the lower fee of 25 centimes is a mandated contribution.



On August 13, 1997, President Clinton signed legislation authorized by Congress permitting the Postal Service to issue the United States' first semipostal stamp. For several years the Postal Service had opposed the issuance of a semipostal stamp.

The legislation permits a surcharge up to 25% of a first class stamp. For a 32-stamp, the surcharge can be as high as 8 cents, yielding a 40-cent stamp. For the first United States semipostal stamp, the surcharge will go towards breast cancer research. The United States Postal Service is permitted one year to establish the amount of the surcharge, as well as the design of the stamp.

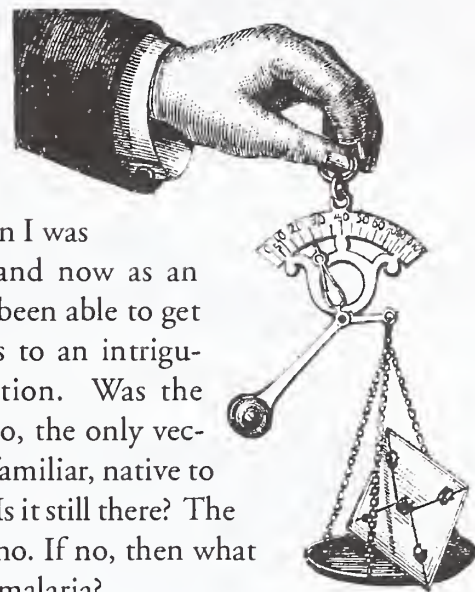
This new semipostal stamp will not be listed in the Scott Standard Postage Stamp Catalogue with the definitive stamps for the United States. Instead, it will be listed in the second group, entitled Semipostal Stamps. The breast cancer stamp will be numbered B1SP1.

CORRESPONDENCE:

John T. Tierney
111 Amherst Avenue
Pawtucket, RI 02860



LETTER TO THE EDITOR:



I read your thoughtful article on malaria, the Pontine Swamp in Italy, the breakdown of the drainage system, caused by World War II, and the value of DDT in making the area liveable again by eliminating the anopheles mosquito [July 1998 issue].

I must tell you of an interesting, perhaps analogous, conundrum about malaria that has puzzled me since I was a kid. This involves malaria in Western New York, an unlikely endemic area for the disease. When I was small, I was packed off every year to summer on Cayuga Lake near Seneca Falls, New York, where my brother-in-law was a general practitioner. It was there that I first heard of "Montezuma Fever." Seneca Falls may be familiar to some as the site of the very first women's rights convention.

The namesake of the fever, Montezuma Swamp, is an extensive area of wetlands north-east of Seneca Falls at the end of Lake Cayuga. It is in fact "high above Cayuga's waters," but at the northern end of the Lake. Montezuma is now a very large protected State Wildlife Preserve. The State has drained much of the area so there is little stagnant water - as the Italian government originally drained the Pontine Swamp. It is now a major stop on the Atlantic flyway for birds going south. In the fall thousands of geese land there every night on their way south from Hudson's Bay, over Lake Ontario, and down the Finger Lakes on their way to the Susquehanna River and Chesapeake Bay.

But back to malaria. In the 1820s the Swamp was a major barrier to the building of the Erie Canal. So many of the Irish labourers who were brought over to dig the Canal became sick with "Montezuma Fever" that it almost stopped construction of the Erie Canal. Modern historians without exception state that "Montezuma Fever" was in fact malaria. In any event it was decided that Irish labourers were expendable, and, though many died, the State pushed on and completed the Canal. Of interest, cases of malaria are now never reported from Sen-

eca Falls.

Back then when I was a smart little kid and now as an adult, I have never been able to get satisfactory answers to an intriguing scientific question. Was the Anopheles mosquito, the only vector for which I am familiar, native to upstate New York? Is it still there? The standard answer is no. If no, then what spread the reputed malaria?

Sincerely,
HERBERT CONSTANTINE, MD

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NINETY YEARS AGO

❧ [SEPTEMBER, 1908] ❧

The lead editorial summarizes the plans for a new Providence City Hospital for Contagious Diseases to be located on a 25-acre site west of Douglas Ave. The cost will be somewhat over \$300,000 and will include a 50-bed scarlet fever ward, a 50-bed diphtheria ward, isolation and observation wards each 20 beds as well as an administration building, powerhouse and laundry. Construction should be completed by January of 1910.

A second editorial summarizes the efficacy of serum treatment for epidemic cerebrospinal meningitis. In a recent year, New York City had experienced a devastating epidemic of meningitis: 5,000 known cases with 70% mortality. This prompted research work by Flexner and Jobling at the Rockefeller Institute to develop an antiserum against

the disease. The serum that they devised was applied in subsequent epidemic clusters, reducing the mortality rate to about 25%. This serum [as with diphtheria antiserum] is derived from a horse, and while still in the experimental stage is nonetheless available to the physicians of Rhode Island through the health department.

A detailed description is provided of a 36 year-old woman who was delivered of a healthy male infant but who suffered a variety of abdominal complaints during the postpartum interval. Charles O. Cooke, MD, gives a daily account of clinical observations and therapies regarding this patient. There were signs of an acute abdominal crisis six days after delivery and a laparotomy revealed a perforated cecum and a contaminated peritoneal cavity. Despite earnest medical efforts, the patient died on the fourth postoperative day, death ascribed to an "autointoxication whose origins we did not discover."

FIFTY YEARS AGO

❧ [SEPTEMBER, 1948] ❧

Louis E. Phaneuf, MD, describes the history of surgical interventions for vesicovaginal fistulae, noting the etiology and the various technical methods to achieve closure. The advantages of a suprapubic drainage in certain difficult cases is stressed. The author notes that before 1834 [when the first successful procedure had been undertaken by Sims] women with this disorder were "doomed to lives of suffering and ostracism."

Edward A. McLaughlin, MD, Director of the State Department of Health, describes the history of state and federal underwriting of hospitals and health programs in Rhode Island. He suggests that the functions of a modern state department of health should include: vital statistics, control of communicable diseases, environmental sanitation, public health laboratory services, maternal and newborn hygiene, and health education for the general public.

Walter C. Weigner, MD, describes a case of acute ascending paralysis in a 60 year-old housewife. The author suggests that this case fits into the category of spinal disease described by Landry.

The lead editorial, entitled Social Insecurity, details the socialization of medicine in the British Isles and decries the National Health Service, in Britain, as a monumental fraud, predicting that American physicians "have no desire to live or to practice in a servile state."

TWENTY FIVE YEARS AGO

❧ [SEPTEMBER, 1973] ❧

The bulk of this issue of the Journal is devoted to the subject of continuing medical education. The lead article, written by Robert V. Lewis, MD, President of the state Medical Society, concludes with these observations: "Organized medicine, and especially the Rhode Island Medical Society, has a prime concern in continuing medical education. We enlist the help of all of you in achieving realistic goals without beclouding the issues by cliches or by over-concerns with the techniques instead of the goals."

Henry Uhl, MD, discusses the feasibility of developing a statewide program for accreditation for continuing medical education efforts, with the Medical Society playing a principal role in the process. A companion paper, by Rutledge Howard, MD, representing the American Medical Association, describes the participation of the AMA in the initiation and surveillance of such educational efforts. Natalie Lawton, librarian to the Westerly Hospital, discusses the increasingly important role of the hospital librarian in arranging and facilitating such programs for the practicing physicians of the community. And Robert Kinder, MD, describes a systematic course of self-study for the practicing ophthalmologists, designed by their peers and sponsored by the American Academy of Ophthalmology.

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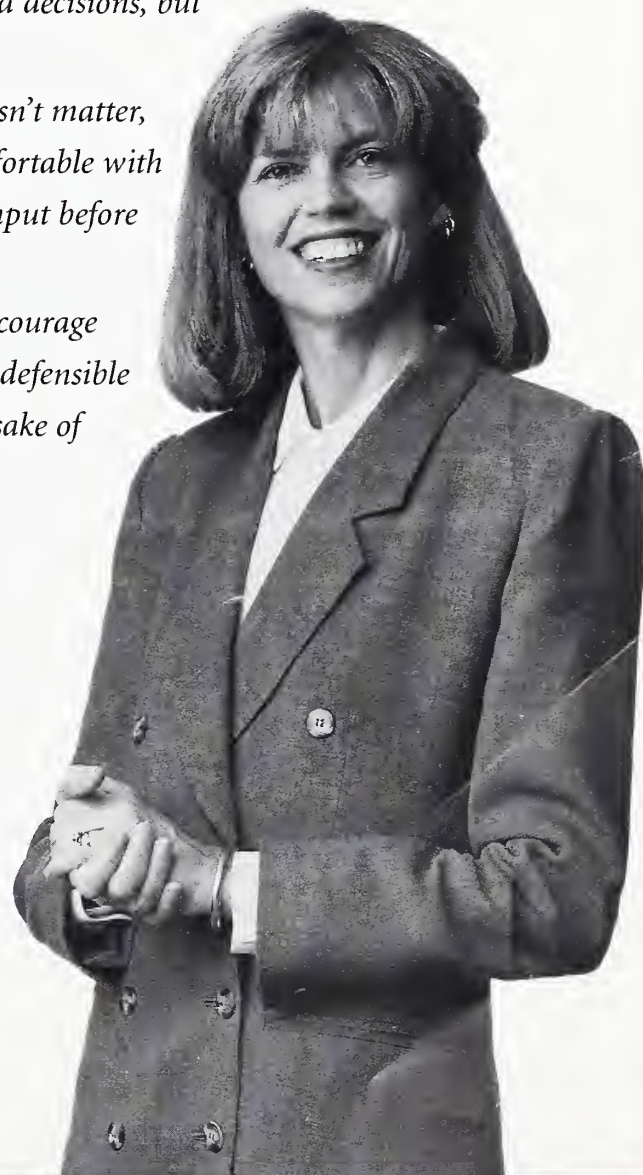
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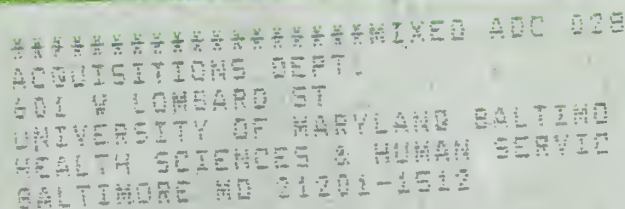
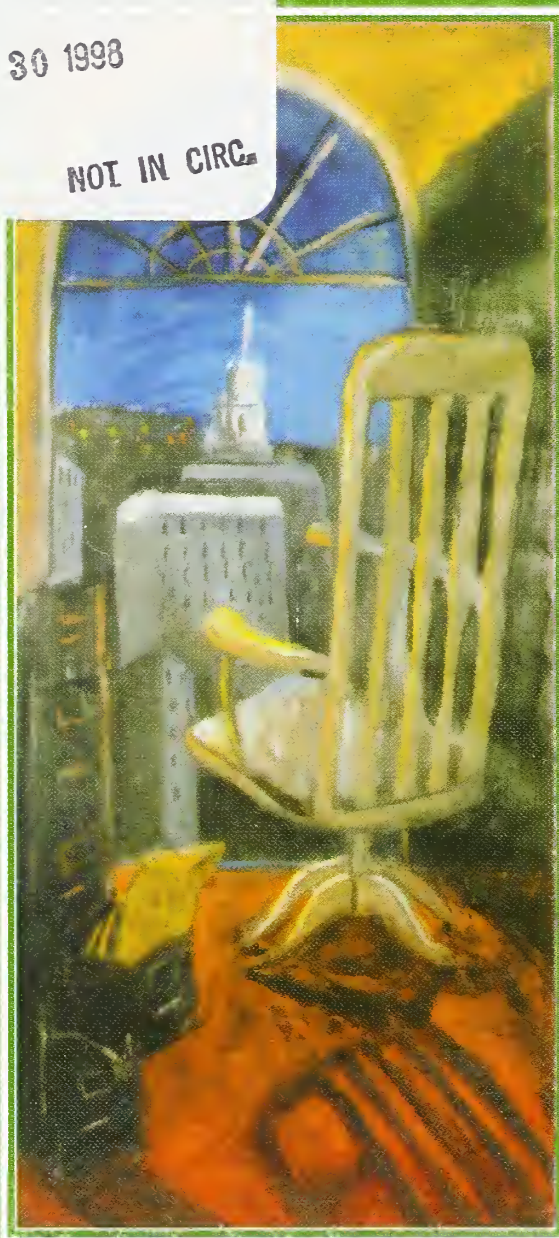
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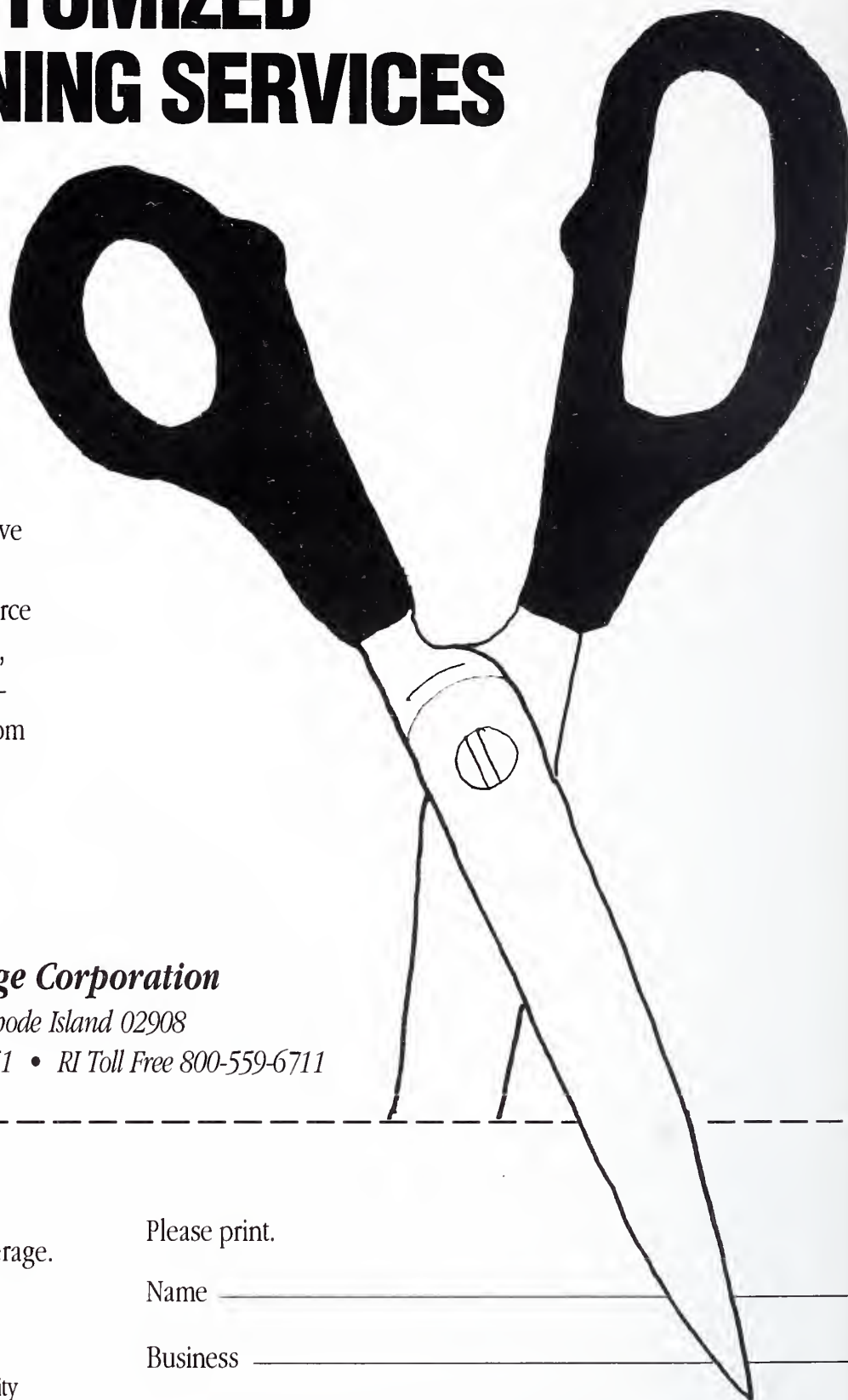
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Correction: The artist for "MARSH," the September cover, is David Baggarly, a Providence artist.

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Oh, How the Frail Have Fallen

Sooner or later great storms abate; passions, even primal ones, eventually subside; but the relentless force of gravity never ceases. To maintain an erect posture, humans are ceaselessly obliged to counteract this remorseless gravitational pull. Postural equilibrium requires such unwavering attention that it cannot be safely assigned to a conscious will subject to all sorts of distractions; rather, protective evolution has relegated this responsibility to a host of subconscious mechanisms. And any lapse in this endless postural vigilance makes humans vulnerable to accidental falls.

Humans are endowed with elaborate neurological systems, both through vision and by other sensing mechanisms, which tell us where we are in relation to the ground. The seemingly simple and easily accomplished act of walking, in truth, is neither simple nor easy; it only seems so when one's brain is fully functional, receiving accurate messages concerning spatial relationships; and the voluntary muscles are fully responsive to autonomic commands from an intact central nervous system; and then, only after years of post-infancy education. But should any of these integrative elements lapse, as so often happens in advanced aging, then balance falters, upright posture is imperiled, and since gravity will not yield, the individual falls.

Falling is a common event; indeed, falling is one of the major reasons why people, young and old, seek help in emergency rooms. Falls are more intimately associated with the frail elderly but adolescents fall just as readily but suffer fewer complications of impact injury such as bone fracture. Some years ago the Rhode Island Department of Health initiated an injury prevention program with particular

emphasis upon falling as a major cause of injury.

These studies, based upon a study of death certificates and hospital discharge records, have yielded the following epidemiological insights: Falls are the leading cause of serious injury requiring hospitalization, greater even than the injuries caused by motor vehicle accidents. [In a typical year, falls are the basis of 78% of hospital admissions secondary to some form of bodily injury.] Falls, particularly in the elderly, are a major cause of death accounting for 41.6% of all fatal injuries in the state.

In Rhode Island, the risk of hospitalization secondary to falls is over fourfold greater in older women than in older men largely because bone density in the postmenopausal woman is less than in males of comparable age. Falls that typically result in some bruising [both to limbs and pride] in a 75 year old man, might cause a serious hip fracture in a 75 year old woman with osteoporosis; 83% of all hip fractures in Rhode Island are in women.

There are ethnic as well as gender differences: Both osteoporosis and associated hip fractures are significantly less frequent in African-Americans. [This observation, noted in numerous retrospective studies on hip fracture, represents one of the very few disease-related advantages in the African-American population.] Elderly who live alone run a higher risk of hip fracture secondary to a fall than do their married counterparts.

Where do serious falls take place? Largely in the home [68%] or in residential institutions [11%]; uncommonly, on the street [5%] or in public buildings [7%]. And the physical nature of the fall? Mainly slipping, tripping or stumbling on the same level



[65%], occasionally falling down stairs [15%].

The suffering and social burdens generated by accidental falls are immense. Beyond the obvious institutional costs [estimated to be over 37 billion dollars per year] is the appalling reality that an avoidable fall, after weeks or months of institutionalization, often converts a previously independent senior to one who will now require protracted assistance in walking and in fulfilling other basic functions of living. A review of the discharge status of those 65 years of age or older who had been hospitalized because of a fall shows that only 11% were able to return to their former level of full independence and able to resume such functions as walking without assistance. Many required extended stays in nursing homes.

Surely gravity will not change. Are falls then inevitable or can commonsense preventive measures be undertaken? Certainly each home can be inspected to determine whether there are environmental hazards such as loose rugs, slippery bathtub surfaces, inapparent objects which might cause a person with failing vision to trip, poor lighting, even confusing floor patterns: factors which might collectively conspire to increase the risk of falling. In addition, might there be medications responsible for episodic dizziness, confusion or slowed reaction time thus imperilling postural integrity? As diligent parents routinely inspect their homes to minimize potential hazards for their children so too might members of the family critically review the surroundings where their elderly relatives live.

— Stanley M. Aronson, MD

Medical Practices in Prehistoric New England

Charles Turek Robinson

CULTURAL OVERVIEW

With the retreat of the Pleistocene glacier about 13,000 B.C., New England's gradually warming climate (still much cooler than today) eventually gave rise to a tundra-like evergreen landscape populated primarily by large Pleistocene game animals. By about 10,000 B.C. (as confirmed by radio-carbon dating of artifactual remains), the first humans (called Paleo-Indians, groups of which had been occupying other parts of the continent since as early as 20,000 B.C.) began to find their way into the region.

These first arrivals to New England consisted of small, scattered bands of hunter-gathers who remained highly mobile in pursuit of the large Pleistocene game animals (including caribou and, as archaeological findings confirm, tremendous mastodon, even right here in Rhode Island!). As the climate warmed and a more modern deciduous forest environment took hold over the next couple of thousand years, however, the Pleistocene game animals retreated north or died off (replaced by smaller, more modern mammals), and Indian culture entered what archaeologists call the "Archaic" phase.

New England's Archaic Indian phase, while still consisting of small groups of mobile hunter-gatherers, gradually saw a change in human movements and subsistence patterns. A more diverse assortment of seasonal resources resulted from continued climatic warming and the attendant change from a tundra setting to a deciduous forest environment (which, by about 4,000 B.C., was not entirely unlike that of today).

These changes rendered Archaic Indian bands more organized and cyclical in their movements than their forbears, the Paleo-Indians (who, as indicated, had erratically followed the movements of the large Pleistocene game animals). Now, the warming forest environment offered seasonal sites

to which Archaic bands returned year after year - sites that offered annual yields of nuts, berries, smaller game, and, especially, annual fish runs. Many such sites, some of them four thousand years old or older, have been located in Rhode Island, especially in close proximity to large bodies of water.

Despite these changes, Native American culture in New England continued to evolve only very slowly, and both the Paleo-Indian culture and that of the Archaic are almost entirely obscured by the mists of vast antiquity. We know little of their non-material cultural traits, including their medical and medicinal practices.

However, very gradual cultural change was to suddenly accelerate between 500 B.C. and 1000 A.D., when agriculture was introduced to New England (probably via trade with Adena Indians to the west). Cultivation of corn, beans, and squash began to gradually spread through the region, especially after 1,000 A.D. Archaeologists refer to this period as the Woodland Period of Native American culture in New England. From 1,000 A.D. on, earlier settlement patterns involving relatively small and dispersed roving bands were, in many parts of New England (including Rhode Island), gradually replaced by less mobile (though not entirely sedentary) settlement patterns centered around agricultural villages with stable food supplies.

Populations increased, and strong identities grew up around these horticultural villages, resulting in the emergence of geographically distinct tribes (the Rhode Island Narragansetts, for instance). In time, these separate tribes not only thought of their territory as uniquely their own, but also developed customs and beliefs unique to their people.

MEDICAL PRACTICES IN TRIBAL NEW ENGLAND

Since New England's various Woodland tribes left no written records, our understanding of aboriginal medicine in prehistoric New England must derive from non-Native sources. When European explorers and English colonists began to reach New England in the late 16th and early 17th centuries, they made detailed written observations of various non-material cultural traits among the various tribes they encountered, including medical and medicinal practices.

Likely, the customs these colonists were observing and writing about (often in wondrous detail) had originated among the Indians much earlier than the period of European contact, so it seems reasonable to conclude that colonial writings, albeit biased at times, especially in matters of religion, afford us a valuable view of Native medicine in the prehistoric, pre-European contact period of Woodland Indian cul-



ture in New England, including Rhode Island. These colonial sources, therefore, although far too many to cite here, will serve as the informational foundation for the remainder of this discussion.

From colonial writings, it is clear that New England's tribes possessed a surprisingly comprehensive level of medical knowledge. They utilized a variety of herbs, plants, and extracts to treat numerous ills, and some of these medicinals are still in use today (including witch hazel, aspirin, and cannabis, for instance - See Appendix). In times of sickness, local Indians could turn to nature for comfort the way we might turn to a pharmacy. From plant sources, they skillfully prepared cough and cold remedies, antiseptics, astringents, emetics, cathartics, diaphoretics, stimulants, narcotics, alternatives, and vermifuges. Developed entirely in a wilderness setting, Indian medicine is deserving of respect. It was apparently more advanced than that of the white colonists who would soon reach New England, especially considering that many early colonists turned not to their own doctors (who dangerously "bled" them for almost all ailments) but rather (at times when inter-cultural relations

were good) to Indian healers.

In general, local Indians were of robust and exceptional physical health, no doubt due to their clean, spacious, non-urban environment. Old World infectious diseases such as smallpox, typhus, malaria, tuberculosis, measles, diphtheria, and probably syphilis were unknown in prehistoric New England (hence, New England's Native populace had never developed immunity against many Old World diseases; this resulted in the deaths of countless Native American New Englanders from European colonial contact).

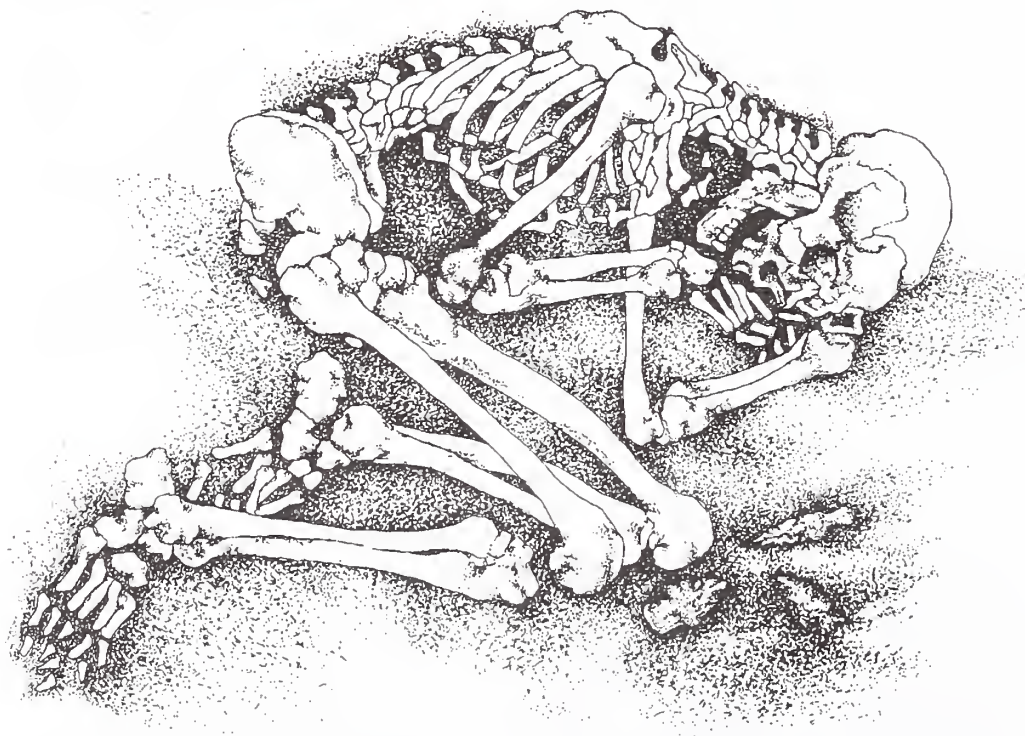
Because of the versatile Algonquin diet, deformities due to malnutrition, such as rickets, were also absent. Obesity was rare, infant mortality low, and life-span generally long (based on excavated burials and the study of associated skeletal remains, an average life-span of sixty seems a good estimate, though there were certainly cases in which individuals lived into their seventies, eighties, and even past a hundred).

Indians took a number of preventive measures against potential health problems. They washed frequently in lakes and streams and anointed their bodies with fish oil or coon grease for

protection against sun and insects. They used walnut oil to dress their hair and give it a sheen. Sweat baths were especially enjoyed (most New England tribes, including, according to Roger Williams, the Rhode Island Narragansetts, built partially underground vaults in which water was thrown upon heated stones to generate steam; the occupants in effect were enjoying the healthful effects of the equivalent of the modern sauna).

In cases of serious injury, the sufferer's family usually called upon the shaman (a "medicine man" trained from youth in spiritual and physical healing techniques) to elicit the assistance of a healing deity, since sickness was thought to be a manifestation of malevolent or angry spirits. Indians considered morality and physical health to be highly interactive, believing that offenses against animals, plants, or other persons could bring ill health to the perpetrator. Considering that human guilt is such a powerful emotion - one that can potentially have physiological implications (loss of appetite, sleep, etc.) - its prospective association with physical illness was not always without validity. In those instances, it was up to the shaman to get his patient to let go of his guilt - to convince the patient of divine forgiveness - a role not unlike that of the modern-day clergyman (or psychiatrist).

The shaman, often donning a colorful animal costume that was representative of a particular healing deity or manito, performed a variety of rituals around his patient, perhaps even a full exorcism in cases where possession was suspect as the cause of illness. These rituals often included chanting and drum-pounding which, far from simply being used for dramatic effect, were undoubtedly quite effective in diverting the patient's mind from his pain. Spiritual reassurance also allowed the patient to further relax, thereby affording his body more strength for actual physical recovery. Thus, the shaman's healing rituals incorporated crucial psychological components. In some cases, he served as a psychiatrist of sorts, who listened to problems and



Artist's rendition of a 400 year-old burial excavated in Tiverton, RI. Skeletal remains of this sort allow archaeologists to make inferences about Native American health and lifespan in New England. Examinations of bone formation and teeth suggest a very healthy culture.

Illustration by B.T. Robinson

Taken with permission from Charles T. Robinson's book, *Asleep Beneath the Meadows* (1992, Universal Press)

offered spiritual advice and comforting rites that could, as noted, convince the patient of divine favor or forgiveness, thereby reducing any worry and guilt that might be underlying the physical condition.

Usually shamans charged a fee for their services, in the form of "tribute" of various items and goods. Like the modern-day physician, their social importance in all of New England's various tribes was also usually rewarded with tremendous social prestige.

Despite their supernatural aura, the shaman's rituals incorporated sound medical procedures, including the use of herbal medicines and the sucking out of poisons and pus from snakebites and wounds. Still, the true

"doctors" of the Rhode Island Narragansetts and other New England tribes were their women, for it was they who were the most knowledgeable in the use of plant curatives for lesser ailments not requiring dramatic shaman magic. When their husbands or children were in pain, they prepared medicinals from wintergreen leaves, which contain aspirin. They employed witch hazel, a liquid extract derived from a shrub, to soothe inflammation - a treatment still used today. They skillfully set broken bones with bark and resin cements. For coughs and colds, they prepared soothing chest balms from the inner bark of the black cherry tree. Sarsaparilla was used to assist kidney function. All in all, the

Indian pharmacopoeia contained several hundred plant remedies (see Appendix), though they varied, to at least some degree, from tribe to tribe.

Nevertheless, regardless of how advanced tribal medicinal practices may have been for a prehistoric wilderness setting, they were useless in protecting the Native populace from the Old World infectious diseases that eventually killed so many of these previously healthy Indians. Old World disease, with a bit of help from the colonial musket, can be regarded as one of the primary factors that led, within a mere 75 years after Plymouth Colony's founding, to the almost complete dissolution of Native American culture in New England.

APPENDIX

The following trees, shrubs and herbs were utilized as medicinals by various New England tribes. It by no means represents a complete listing of all such herbal medicines used in New England.

Common Name	Botanical Name	Bodily Influence
Alder	<i>Alnus rugosa</i> (DuRoi) Spreng	Astringent, Cathartic
Balsam Fir	<i>Abies balsamea</i> (L.) Mil	Expectorant, Stimulant
Blackberry	<i>Rubus allegheniensis</i> Porter	Astringent, Tonic
Bloodroot	<i>Sanguinaria canadensis</i> L.	Emetic, Diuretic
Boneset	<i>Eupatorium perforliatum</i> L.	Stimulant, Aperient
Butter Nut	<i>Juglans cinerea</i> L.	Cathartic, Vermifuge
Cedar, Red	<i>Juniperus virginiana</i> L.	Medicinal (various)
Cherry, Red	<i>Prunus virginiana</i> L.	Sedative, Tonic
Cranberry	<i>Vaccinium macrocarpon</i> Ait.	Uncertain
Ginseng	<i>Panax quinquefolius</i> L.	Stimulant, Demulcent
Hemlock	<i>Tsuga canadensis</i> (L.) Carr.	Uncertain
Hops	<i>Humulus Lupulus</i> L.	Sedative, Diuretic
Hemp	<i>Apocynum cannabinum</i>	Diverse
Juniper	<i>Juniperus communis</i> L.	Stimulant, Diuretic
Lady's Slipper	<i>Cypripedium reginae</i> Walt.	Antiperiodic, Nervine
Lobelia	See "Indian Tobacco"	
"Indian Tobacco"	<i>Lobelia inflata</i> L.	Stimulant, Relaxant
Milkweed	<i>Asclepias syriaca</i> L.	Diaphoretic, Other
Oak, Red	<i>Quercus rubra</i> L.	Antiseptic, Astringent
Partridge, Berry	<i>Mitchella repens</i> L.	Parturient, Tonic
Pennyroyal	<i>Hedeoma pulegioidis</i> L.	Corrective, Nervine
Pyrola	<i>Pyrola elliptica</i> Nutt.	Antispasmodic, Tonic
Raspberry, Red	<i>Rubus idaeus</i> L.	Stimulant, Tonic
Rattlesnake Root	<i>Polygala senega</i> L.	Snakebite antidote
Sarsaparilla	<i>Aralia nudicaulis</i> L.	Alternative, Demulcent
Skunk Cabbage	<i>Symplocarpus foetidus</i> Nutt.	Stimulant, Expectorant
Sumac	<i>Rhus glabra</i> L.	Astringent, Tonic
Sweet Flag	<i>Acorus Calamus</i> L.	Aromatic, Stomachic
Tobacco	<i>Nicotinia rustica</i> L.	Stimulant, Analgesic
Wintergreen	See "Pyrola"	

Appendix taken with permission from Charles T. Robinson, *Native New England: The Long Journey*, Covered Bridge Press, 1996.

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On the Development of the Surgical Intensive Care Unit: The Rhode Island Experience

Steven Schechter, MD, Carmine J. Capalbo, MD, J. Robert Bowen, MD, Thomas Perry, Jr., MD

The surgical intensive care unit has become a cornerstone in treating critically ill surgical patients. Following World War II, the scientific understanding of disease mechanisms mushroomed along with the advancement of surgical technique and technology. The end result was the ability to support critically ill surgical patients with severe metabolic derangements. Basic medical or surgical wards could not rise to the occasion and take care of these special patients. Vital sign measurements could not be performed with enough frequency in patients with dramatic third spacing of fluid. Moreover, the clinical picture of postoperative septic syndrome or myocardial infarction demanded minute-by-minute monitoring. Clearly, the patient who developed organ failure could not be safely treated on a general ward. The physicians and hospi-

tal administrators, with help from nursing, had to develop "special rooms" to handle these new patients. The evolution of these special rooms to the Surgical Intensive Care Unit (SICU) may have occurred simultaneously at various institutions across the continent or western world. The experience at the Rhode Island Hospital in Providence, Rhode Island, stands out. This article will explore the development of the SICU through the efforts of one surgeon, Dr. J. Murray Beardsley (Figure 1).

DR. J. MURRAY BEARDSLEY: THE SURGEON

Dr. J. Murray Beardsley, son of a sea captain, was born in Nova Scotia, Canada, in 1900. He received his MD degree in 1928 at Dalhousie University in Halifax. Marrying Sarah I. Morse of Providence, Rhode Island, in 1928, he remained closely bound to that city. His internship at the Rhode Island Hospital was completed in 1931 and advanced surgical training was completed at the New York Skin and Cancer Hospital. Afterwards, he practiced general surgery in Providence. During World War II, he served in the army as a major in the Forty-Eighth Evacuation Hospital in China, Burma, and India. He eventually became chief of surgery at the Burma unit. In 1950, he was made surgeon-in-chief at the Rhode Island Hospital. Dr. Beardsley was always deeply involved in the surgical residency program there and strove for its excellence. He is credited with instituting the surgeon-in-chief Pro

Abbreviations Used:

SICU surgical intensive care unit

Tempore (visiting professor program). During his tenure he achieved national recognition for his contributions to surgery of the esophagus, hiatal hernia repair, and for his pioneering work in the development of special facilities for critically ill surgical patients.

SPECIAL CARE UNIT: THE CONCEPT

Dr. Beardsley recognized that the post-operative care of certain surgical patients had become problematic. After World War II, advances in medicine had increased the number and complexity of surgical procedures, which created a new breed of critically ill patients. Advanced gastrointestinal, pulmonary, and cardiac surgeries were being undertaken on patients with underlying physiologic abnormalities who needed special attention requiring specially trained personnel. Although private duty nurses were often recommended, the average patient could not afford them and their level of training was variable. At this time, in the 1950's, Rhode Island was experiencing a shortage in nursing personnel. Auxiliary personnel such as practical nurses and hospital aids had often compensated for the lack of graduate nurses. Dr. Beardsley wrote in 1956, "the more efficient approach to the problem is to segregate all seriously ill surgical patients in a single unit that is staffed by personnel especially trained for the job. The care of this type of patient requires specialized training that is on a par with that of personnel assigned to an operating team."¹ Usually a "special room" holding three critically ill patients was set up on the surgical ward staffed by the



Figure 1. Photo of J. Murray Beardsley.



Figure 2. Photo of special care unit. Circa, 1956.

floor head nurse along with a nursing student.

In a nutshell, Dr. Beardsley elegantly stated the philosophy that would set the stage for the SICU. What started out as "special rooms" for the critically ill patients on surgical wards became a special care unit.

Planning for this new unit began in 1952 and culminated in 1955 with the erection of the new Rhode Island Hospital. Supported by an \$84,000 grant from the Hartford Foundation,² a new 28-bed special care unit on the fourth floor opened, just above the operating theater.

The architectural design of the unit incorporated two adjacent wings on the same floor. One wing was for medical patients. The nursing station was situated in the center of each wing. The liberal use of glass partitions made it possible to observe all patients from the nursing station (Figure 2). Resident sleeping quarters, laboratory, minor surgery room, dressing rooms, and waiting rooms were designated. Each patient bed had a suction outlet, oxygen, and sphygmomanometer on the wall. Staffing consisted of a complement of graduate nurses along with a surgical resident.

SPECIAL CARE UNIT: THE DOCUMENTATION

The evolution of the special care unit into the modern SICU occurred over the next forty years. This successful centralization of critically ill surgical patients sprang up not only across the United States but through western countries. Can one be certain that the concept and creation of the first special care unit occurred in Rhode Island? One year after the special care unit opened, Dr. Beardsley wrote: "the success of the venture has been most gratifying and has more than justified its existence. Since publication of Beardsley's article in the *Journal of the American Medical Association*, there has been an enormous interest expressed by hospitals in other parts of the country. In addition, many hospital and nursing directors have visited our hospital to obtain more detailed information and to see this unit in operation."³

Clearly, this demonstrates an intense interest by other hospitals to develop their own special care units. Another valuable piece of evidence is presented in Figure 3: a certification of appreciation for the presentation of the exhibit entitled, "surgical special care unit" at the Clinical Congress of the American College of Surgeons meeting in Chicago (1961). A picture of the original booth is shown in Figure 4. At the center is a reconstructed model of the special care unit that Dr. Carmine Capalbo guarded carefully while on the train from Providence to Chicago.⁴ If these units were common place, then they would have been of little interest to the exhibition. Dr. J. Murray Beardsley presented a paper on the Rhode Island Hospital surgical special care unit in Dublin, Ireland, at the International Society of Surgery (XIX Congres de la Societ  Internationale de Chirurgie) in September, 1961.

The hospital administration started to evaluate the special care unit's economic impact early on. Herluf V. Olsen, Jr., an Assistant Director of the Rhode Island Hospital, presented a talk, "Are specialized units the answer to better patient care and lower costs?" at the mid Atlantic Hospital assembly May 21, 1959.

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SCIENTIFIC EXHIBITION

CLINICAL CONGRESS, CHICAGO, OCTOBER 2 TO 6, 1961

This Certificate of Appreciation for the Presentation of the Exhibit Entitled

SURGICAL SPECIAL CARE UNIT

is Awarded to

J. Murray Beardsley, M. D., F. A. C. S., J. Robert Bowen, M. D., F. A. C. S.,

and Carmine J. Capalbo, M. D.

John Paul North
Director

Figure 3. Certificate of appreciation for the presentation of the exhibit entitled, "Surgical Special Care Unit" at the Clinical Congress of the American College of Surgeons meeting in Chicago (1961).

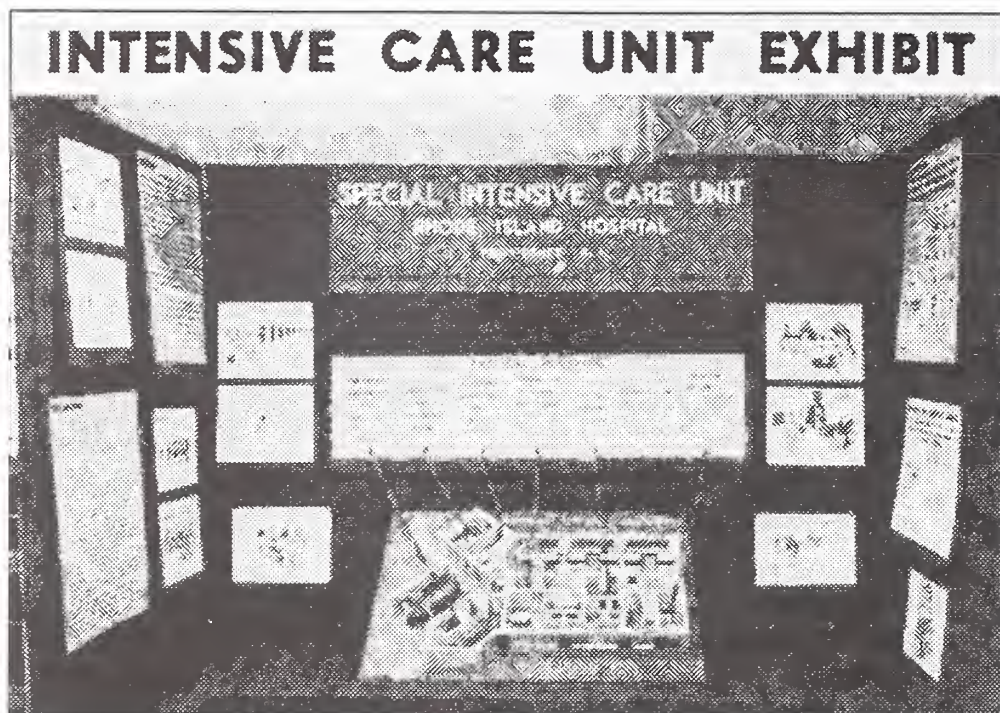


Figure 4. Photo of original booth at the clinical congress of the American College of Surgeons meeting in Chicago (1961).

SPECIAL CARE UNIT: THE EVOLUTION

Dr. J. Murray Beardsley retired in 1961 as the chief of surgery at the Rhode Island Hospital and was replaced with a full-time chief of surgery, Dr. Lester L. Vargas. Although the first open heart operation in Rhode Island was done by Dr. Dwight Harken from Brigham and Womens Hospital in Boston, Massachusetts, with J. Murray Beardsley assisting, Dr. Vargas introduced an open heart surgery program at Rhode Island Hospital in April of 1959. Timing could not have been better since patients post open heart surgery were ideal candidates for the special care units. The evolution from special care units to the modern day SICU had begun.

As newer surgical procedures for congenital and acquired heart disease, organ transplantation, major oncologic surgical resections and better handling of trauma were developed, the surgical trauma intensive care unit had a parallel technological development. The addition of mechanical ventilators and hemodynamic monitoring equipment had finally given the SICU what Dr. Beardsley intended - the status of an operating theater. Although the advanced equipment of today's SICU dwarfs the original special care units of the 1950's, the philosophy remains the same.



CONCLUSION

Dr. J. Murray Beardsley is credited with developing and instituting one of the first surgical intensive care units in the United States and possibly the world. The development of the surgical intensive care unit at the Rhode Island Hospital is clearly documented. Presentations of the Rhode Island Hospital experience with its surgical intensive care unit at national and international meetings support and document the originality of this concept in patient care along with its founder.

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Flu Vaccination Decreases Relative Morbidity Risk for People with Diabetes

Frank Vinicor, MD, MPH

People with diabetes are more likely to die from complications of influenza than people without hyperglycemia. From 1985 through 1987, national surveys on the health and mortality of the U.S. civilian population concluded that people with diabetes are about three times more likely than people without diabetes to die from flu and pneumonia-related complications. Each year, 10,000 to 30,000 people with diabetes die from complications of the flu and pneumonia. During flu epidemics, people with diabetes are six times more likely than people without diabetes to be hospitalized, and their death rates may increase 5 to 15%. This risk is particularly high when additional risk factors such as cardiovascular disease and kidney disease are present.

It is estimated that immunizations could prevent up to 80% of deaths associated with the flu, yet nearly two in three adults with diabetes do not get a simple, safe flu shot. Aggressive efforts need to be taken to increase influenza immunization levels among people with diabetes in order to decrease flu-related morbidity and the number of preventable deaths.

Typically, physician-regulated diabetes care emphasizes aggressive control of the disease to retard the onset and progression of long-term complications affecting the eyes, kidney, and cardiovascular and nervous systems. Concentration may be only on diabetes itself, not on the overall health of the patient. As a result, we may overlook preventive measures, such as flu shots, that we would utilize with our patients without diabetes.

CDC is launching a national awareness campaign this fall to encourage people with diabetes to get a flu shot before flu season, which is generally November through March. We also recommend a pneumococcal vaccine for people with diabetes. Nationally representative data suggest that less than one in six persons with diabetes are immunized against pneumococcal pneumonia.

You can help by including influence and pneumococcal vaccinations as part of a regular diabetes management program. Please encourage your patients to be vaccinated to protect themselves from these preventable risks and "take control of their diabetes."

Frank Vinicor, MD, MPH, is Director, Division of Diabetes Translation, Centers for Disease Control and Prevention.

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Medicare Medical Policy Development

Parker J. Staples, MD

Medicare medical policies are, simply put, published documents specifying under what conditions and circumstances specific medical items, services, treatments, procedures and technologies can be paid for under the Federal Medicare Program. It is important for physicians to know how these medical policies are developed and implemented since all policies have payment ramifications to a greater or lesser degree. This article will summarize how this developmental process works for three of the most important types of Medicare medical policies: Acts of Congress, national coverage decisions, and local medical review policy.

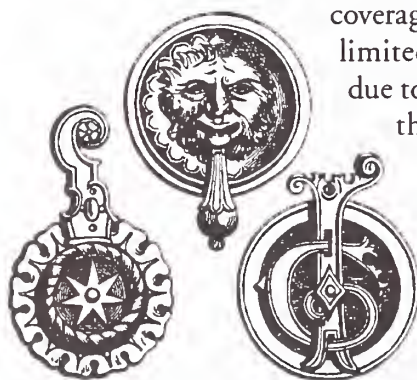
ACTS OF CONGRESS

Acts of Congress are passed from time to time that grant Medicare benefits to beneficiaries in certain areas where no such benefits would have been possible under the original Social Security Act of 1965. These Congressional decisions invariably liberalize existing law, tend to be extremely popular with beneficiaries and physicians, and are binding on all Medicare contractors. These legislative coverage decisions usually involve granting benefits for screening procedures not ordinarily covered under the original Medicare legislation. The most recent example of Congress at work occurred in the Balanced Budget Act of 1997 when benefits were extended to screening determinations for bone mineral density, colorectal screening, and PSA determinations (beginning in the year 2000). These Acts of Congress until recently appeared to be infrequent, but they may rapidly increase if suppliers, drug manufacturers, physicians and special interest groups increasingly perceive that politics can quickly and profitably be substituted for critical scientific evaluation in the Medicare coverage decision arena.

NATIONAL COVERAGE DECISIONS

National coverage decisions, if and when made by the Health Care Financing Administration (HCFA), are also binding on all Medicare Contractors. These decisions have the distinct advantage of ensuring uniform Medicare coverage for a particular item or service anywhere in the United States and Puerto Rico. National

coverage decisions are, however, limited in number primarily due to the sheer complexity of the governmental decision-making process. All important national coverage decisions ultimately appear either in the Federal Register or in the Coverage Issues



Abbreviations Used:

AHCPR	Agency for Health Care Policy Research
CAC	Carrier Advisory Committee
CIA	Coverage Issues Appendix
CMD	carrier medical director
HCFA	Health Care Financing Administration
HMO	health maintenance organization
LMRP	local medical review policy
MCM	Medicare Carrier's Manual
MCO	managed care organization
OCHAMPUS	Office of Civilian Health and Medical Program of the Uniformed Services
OHTA	Office of Health Technology Assessment
PSA	prostate specific antigen
TAC	Technical Advisory Committee

Appendix (CIA) of the Medicare Carrier's Manual (MCM). Some examples of these coverage decisions include policies on heart and lung transplants (covered), platelet transfusions (covered), thermography (noncovered) and transcendental meditation (noncovered).

Until very recently, the primary engine of this national policy development was the HCFA Technical Advisory Committee (TAC). The TAC was composed of representatives from the Agency for Health Care Policy Research (AHCPR), the Food and Drug Administration, the National Institutes of Health, the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), selected carrier medical directors, physician and dentist employees of HCFA, and HCFA staff. The TAC was authorized to make national coverage policy recommendations to HCFA as well as to refer topics to AHCPR and the Office of Health Technology Assessment (OHTA) for comprehensive technology assessment when appropriate. However, as of late 1997, the TAC was dissolved by HCFA based on a legal challenge from the private sector alleging that the TAC was in direct violation of the Federal Advisory Committee Act. As a result, national coverage decisions are expected to emerge slowly if at all in the foreseeable future. A direct corollary to this observation is that medical coverage decisions made at the Carrier level will assume new dimensions both in terms of timeliness and importance.

LOCAL MEDICAL REVIEW POLICY

Local medical review policy (LMRP) development is by far the most important process by which Medicare Carriers devise and implement coverage guidelines. These local policies are carrier-specific and usually address perceived

community or regional medical procedure or service overutilization issues relative to national norms. The most significant difference between national and local policy development is that the medical community within a Carrier's jurisdiction is asked to participate in the policy-making process. This process, referred to as the Notice and Comment process, was first articulated by HCFA in April of 1989 and subsequently required of all carriers on and after January 1, 1991. Proposed policies in draft form are sent to all members of the Medicare Carrier Advisory Committee (CAC), a committee composed of representatives from each of the state's approximately 30 medical specialty/subspecialty societies. The CAC also includes representatives from the state medical society, the state osteopathic society, the Hospital Association of Rhode Island, the principal clinical coordinator of the PRO and medical directors representing the state's health maintenance organizations. This committee meets three to four times during the year to discuss with the Carrier Medical Director (CMD), carrier staff and HCFA regional office staff all medical policies proposed for local implementation. Any Medicare administrative issues

The most significant difference between national and local policy development is that the medical community within a Carrier's jurisdiction is asked to participate in the policy-making process.



thought to have an immediate or upcoming impact on the physician community are brought up for discussion as well. Though the CAC functions in a purely advisory capacity, its influence in shaping and refining local Medicare policy is of considerable importance. The composition and specialty designations of each of the 1998 Medicare Carrier Advisory Committee members are given at the end of this article.

CAC representatives are expected to disseminate proposed LMRPs to colleagues in their respective State and

specialty societies for further comment along with any other information of importance about the Medicare program, particularly upcoming administrative changes. As many policies and changes may impact only a small segment of the Rhode Island physician community at any one time, this dissemination process depends on the issues at hand and is at the discretion of the CAC representative. The policy distribution and comment period lasts for a minimum of 45 days. The Carrier Medical Director reviews and responds to all suggestions received and, where appropriate, incorporates reasonable changes into the final policy document. A local policy becomes final 30 days after its publication to the medical community at large through the Carrier's news letter or monthly bulletin. Most importantly, local policies can be and frequently are modified after implementation based on continuing feedback from the Rhode Island physician community.

One of the primary disadvantages of Medicare policies developed locally is that they may differ, sometimes substantially, from policies on similar topics developed by other carriers. Reasons for these differences are varied and may reflect local practice pat-

Announcement:

Rhode Island Public Health Association

Rhode Island Public Health Association (RIPHA), an affiliate of the American Public Health Association, formed in late 1997. It is a non-profit tax-exempt professional organization concerned with the advancement of public health throughout the state. RIPHA brings together professionals in a unique and multi-disciplinary environment for professional exchange, study and action.

OBJECTIVES INCLUDE:

- protect and promote interest in public health;
- increase professional standards in the health field;
- provide opportunity for communication and exchange of ideas;
- present professional education programs in the science and practice of public health;
- encourage cooperative efforts to support public health initiatives among public and private organizations and companies engaged in public health activity;
- advocate for improvement to public health policy, program and service in Rhode Island;
- promote training opportunities through which new skills and techniques for improved services may be developed.

The office is located at One Turks Head Place (Suite 1450), Providence, RI. Phone number is (401) 273-2286.

Past programs included educational seminars on heart disease and public health initiatives, ending with our annual meeting, where Dr. Quentin Young, president, American Public Health Association, was the keynote speaker.

Programs for 1998 include diabetes and environmental issues.

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terns, differing expert opinions, and variations in the enthusiasm of the Carrier Medical Director/CAC for developing liberal versus restrictive coverage indicators for any given service or procedure. Fortunately, CMD national and regional CMD meetings promote policy uniformity as do "template," or model policies developed by CMD workgroups for local implementation through the notice and comment process by any carrier who wishes to use them. The "template" policy process appears to capture the best possible combination of an initially uniform document later modified for local use through the Notice and Comment process. Some of the currently active CMD workgroups include workgroups on: Urology, Clinical Laboratory Services, Interventional Radiology, Cardiology, New Technology-Medical, New Technology-Surgical, Ophthalmology, Surgery,

Pulmonary Rehabilitation and Psychiatry.

It is tempting as a Carrier Medical Director to think of each medical policy as a Carrier-Community agreed-upon document incorporating the best medical opinions available, state-of-the-art practice guidelines, and outcomes research data when available. However, in reality this ideal is rarely if ever achieved. Instead, most policies appear to be practical compromises between physicians seeking unlimited freedom from today's medical practice resource constraints and the Carrier's perception of medical necessity prospectively applied to a drug, service or technology for Medicare program safeguard purposes.

MEDICARE POLICY AND MANAGED CARE

No discussion of Medicare policy development would be complete with-

out noting that all Medicare beneficiaries enrolled in an HMO/MCO are entitled to receive at least the services that are covered by fee-for-service Medicare in the Rhode Island geographic area. Thus, when a Congressional mandate, a HCFA national coverage decision or a local carrier medical policy governing a particular Medicare benefit exists, these same covered benefits must be offered to beneficiaries enrolled in an HMO/MCO of any type. These latter plans are free to be more generous than fee-for-service Medicare in covering a particular policy-governed service or benefit if they wish, but they cannot be less generous. Questions on this or any Medicare coverage issue can always be addressed directly to the Medicare Carrier Medical Director at Blue Cross & Blue Shield of Rhode Island, 444 Westminster Street, Providence, RI 02903 or by phone at (401) 459-1701.

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The Physicians of Rhode Island: A Summary of Disciplinary Actions Taken by the Board of Medical Licensure and Discipline [1987-1998]

Milton W. Hamolsky, MD, Nikki Samaras Deary, and Stanley M. Aronson, MD, MPH

During the annual meeting of the Rhode Island Medical Society in 1988, the Rhode Island Board of Medical Licensure presented its first progress report.¹⁰ This prior report summarized the licensure efforts undertaken by the state since 1895 when physicians had first been required to obtain licenses to practice. This older report also provided information on the 1896 legislative definitions of such terms as "physician" and "practice of medicine"; the establishment, in 1976, of a separate and semi-autonomous Board of Medical Review; and finally, the creation of a combined Board of Medical Licensure & Discipline, effective January 1, 1987.

That first report to the Society membership touched further upon such issues as the reasons why the separate licensure and disciplinary functions had been transferred to a single board; the composition of this Board [the first, and

still the only State Board with equal representation of physicians and public members]; the nature and conduct of investigations, dissemination of findings of unprofessional actions, range of sanctions, consent orders, the observance of due process, confidentiality of proceedings until a final judgment is rendered, and appeal mechanisms.

In recent years the Board has provided published reports, at approximately yearly intervals, on the licensure process and trends in the background and training of newly licensed physicians in the state of Rhode Island.¹⁻⁸ The present report represents the first published summary of disciplinary actions undertaken by the Board in the first 11 years and nine months of its existence [January, 1987, to September, 1998.]

State law specifies that the Board shall be composed of four licensed physicians who possess the degree of doctor of allopathic medicine, one of whom shall

be a full time medical school faculty member; two licensed physicians who hold the degree of doctor of osteopathic medicine; six public members, one of whom shall be an attorney and one of whom shall be at least 60 years of age; one hospital administrator; and the Director of the state Department of Health who shall serve as chairperson of the Board.⁹

Rhode Island Law declares that "Any person, firm, corporation or public officer may submit a written complaint to the Board charging the holder of a license to practice medicine or limited registrant with unprofessional conduct, specifying the grounds therefore. The board shall review all complaints..."

⁹ During the past six years the board has investigated 3,031 written complaints, and, during this interval, has rendered a final judgment of unprofessional conduct in 116 instances.

Table 1 defines the categories of unprofessional conduct identified by Rhode Island law, cites the relevant sections of the Rhode Island State statute pertaining to disciplinary actions, and

Table 1

Cases of Unprofessional Conduct (UPC) [1987-1998]

Nature of Unprofessional Conduct	No. Physicians**
Abuse of controlled substances [5]*	17
Immoral conduct [7]	10
Fraudulent billing [16]	4
Professional or mental incompetency [18]	10
Incompetent, negligent or willful misconduct [19]	62
Action taken by another state [for activity which would have been deemed unprofessional conduct in Rhode Island] [21]	47
Failure to furnish Board with legally requested data [23]	4
Violation of Dept Health rules, regulations [24]	4
Subverting licensure examination [25]	4
Medical malpractice [28]	7
Deceptive advertising [2]	1
Failure to report legally required information [9]	1
Conviction of crime [felony, moral turpitude] [3]	2
Filing false reports [8]	3
Failure to meet standards of Peer Review bodies [27]	3

*: Number in parenthesis represents the relevant section of state law pertaining to medical licensure and discipline [9].

**: Some physicians guilty of more than one case of UPC.

Table 2

Categories of Disciplinary Actions Taken by Board

Category	No. of Physicians
License revocation	13
License suspension*	30
Voluntary surrender of license	26
Restrictions placed upon practice [probation, required supervision, remedial training]	28
Written reprimand	62
Denial of licensure	9

*: Nine of these were summary suspensions, such actions undertaken by the Director of Health. ["The Director may, temporarily, suspend the license of a physician or limited registrant without a hearing if the Director finds evidence in his or her possession that indicates that a physician's or limited registrant's continuation in practice would constitute an immediate danger to the public. . . . a hearing by the board must be held within ten [10] days after such suspension has occurred." Section 5-37-8 of Rhode Island Board of Medical Licensure & Discipline Laws.] [9]

Table 3

Cases of Unprofessional Conduct by Primary Medical Specialty*

Specialty	No. Physicians in Specialty	No. Cases Investigated	No. Instances UPC*	Risk per year+
Internal Medicine	1,070	511	31	0.5%
Ob/Gyn	303	312	16	0.9%
Pediatrics	403	135	12	0.5%
Family Medicine	477	252	11	0.4%
General Practice	63	20	12	3.2%
Emergency Medicine	204	166	12	1.0%
Anesthesiology	251	67	7	0.5%
Psychiatry	419	177	6	0.2%
General Surgery	247	273	5	0.3%
Orthopedic Surgery	192	275	4	0.3%
Totals	3,629	2,188	116	0.5%

*: Specialties are self-declared by the involved physician. Specialties with three or fewer judgments of unprofessional conduct [eg, radiology, neurology] were not included in this table.

*: UPC = Unprofessional Conduct

+: Risk/year, per specialty, determined by the following formula. The product is multiplied by 100 to convert risk to a percent:

$$\text{Risk/yr} = \frac{\text{No. instances of UPC per specialty}}{\text{No. physicians in specialty}} \times \frac{1}{6 \text{ [no. yrs]}} \times 100$$

indicates the numbers of physicians found guilty of unprofessional conduct in each of these categories since 1987.

Table 2 details the disciplinary actions taken by the Board in following its judgment of unprofessional conduct.

Table 3 summarizes instances of unprofessional conduct according to the physician-declared medical specialty compared to the overall numbers of physicians in each of these specialty groups, and the numbers of cases opened for investigation following complaints initiated by patient-allegations, civil suits, insurance company settlements or complaints put forth by another state agency [eg, Medical Examiner's Office, State Police.]

Table 3 also offers the relative risk of unprofessional conduct judgment per specialty [eg, the average risk of an adverse judgment by the Board, for a Rhode Island obstetrician, is 0.4% per year.] During this 6-year interval, the Board conducted 2,188 investigations. A judgment of unprofessional conduct was rendered in 5.3% of investigations while in 94.7% of cases, no unprofessional conduct was determined. Allegations, brought by patients, were greater per practicing physician in the surgical specialties [obstetrics/gynecology, general surgery, orthopedic surgery] although the risk of adverse judgment for surgical and

nonsurgical specialties was about the same. For example, during the past 11 years, 275 official complaints had been registered against 192 orthopedic surgeons. Each complaint was carefully investigated by the Board but only 4 of the 275 complaints [1.45%] were eventually judged to represent unprofessional conduct.

Tables 1 and 2 represent almost 11 years of Board experience. Table 3 represents the most recent 6 years (since computerization of the records.)

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THE CREATIVE CLINICIAN: CASE OF THE MONTH

The practice of medicine is an art, not a trade; a calling, not a business ... – WILLIAM OSLER, Aequanimitas

Editor: Anthony Mega, MD; Co-editor: Fred J. Schiffman, MD

FISH As an Adjunct To Conventional Cytogenetics

Hon Fong L. Mark, PhD, FACMG, David N. Alter, MD, and Anthony Mega, MD

*This article is based in part on the research for Dr. Mark's invited editorial for *Cancer* (1998) and her chapter from her book, *Medical Cytogenetics* (Marcel Dekker, NY, in press).

Molecular cytogenetics using fluorescent *in situ* hybridization (FISH) is an extremely useful adjunct technique to conventional cytogenetics. We reported on the advances in molecular cytogenetics using FISH in 1994.^{1,2} Since then, a number of commercial probes have been FDA-approved. These include certain chromosome enumeration probes for cancer analysis. The present paper illustrates the utility of FISH as applied to hematopoietic malignancies.

CASE HISTORY

The patient is a seventy-two year old man referred by his personal physician for hematologic evaluation for an anemia (HGB 11.9 g/dl, HCT 37%) with macrocytosis (101 fL) and markedly elevated serum ferritin level (1219 ng/ml). His past medical history was significant for severe rheumatoid arthritis and transitional cell carcinoma of the bladder (grade 2/3 without invasion) diagnosed in December, 1996, which was treated with BCG for three months. An MRI done by his physician was significant for liver changes consistent with early hemochromatosis.

Hemochromatosis was ruled out secondary to a transferrin saturation of 22% and a total iron of 27 mg/dl. The elevated serum ferritin level was attributed to the patient's history of severe rheumatoid arthritis. The macrocytic anemia, in light of normal B-12/folate studies, a corrected reticulocyte count less than 1% with an elevated LDH (963 IU/L) and Coombs' test positive, was thought to represent an autoimmune mediated hemolytic anemia. This, and his arthropathy were treated with steroids which resulted in an increase in his hemoglobin and lessening of arthritic symptoms. However, the macrocytosis (104 fL) persisted. A normal serum protein electrophoresis ruled out multiple myeloma. Bone marrow biopsy and aspiration were also performed which had a normal (500 cells) differential with no other significant pathologic findings and no evidence of myelodysplasia. FISH was done on the aspirate.

Abbreviations Used:

CGH	comparative genomic hybridization
FDA	Food and Drug Administration
FISH	fluorescent <i>in situ</i> hybridization
GTG	G-banding using trypsin and gremsa stain
MRI	magnetic resonance imaging
SKY	spectral karyotyping

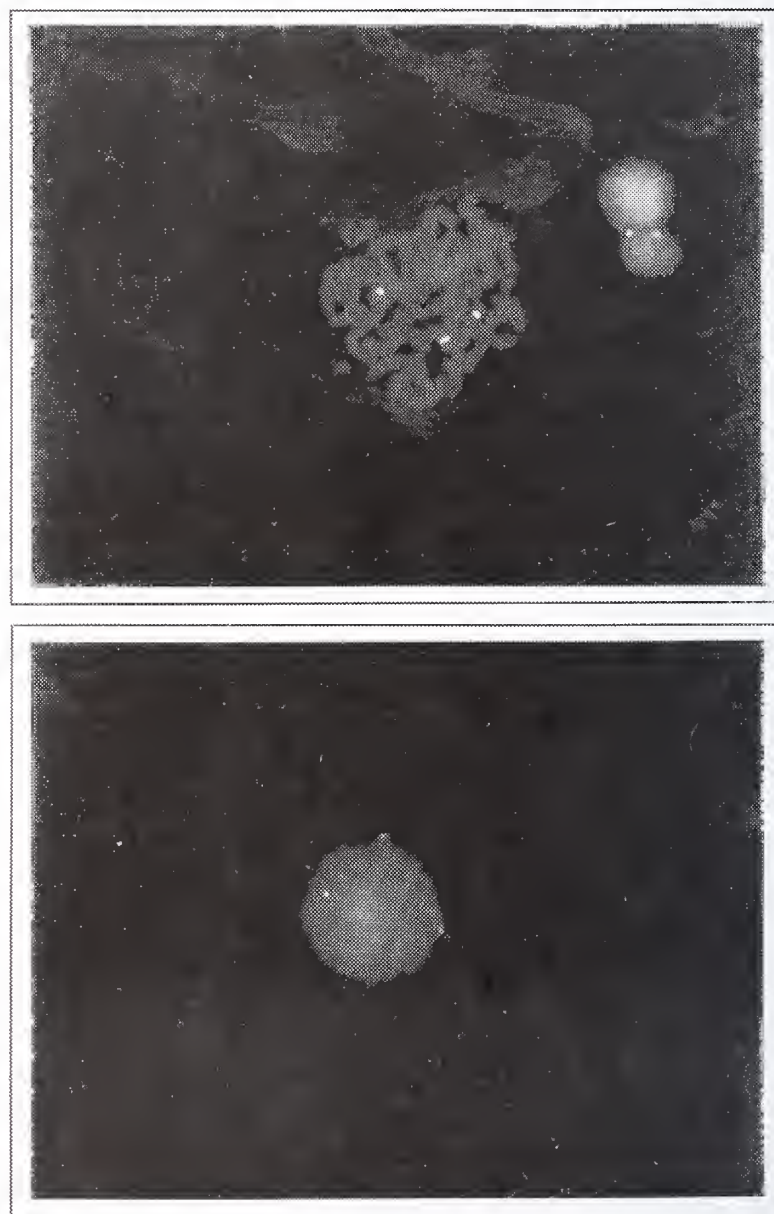


Figure 1. a. FISH using a chromosome 8-specific α -satellite probe (Oncor, Gaithersburg, MD), demonstrating three copies of chromosome 8.

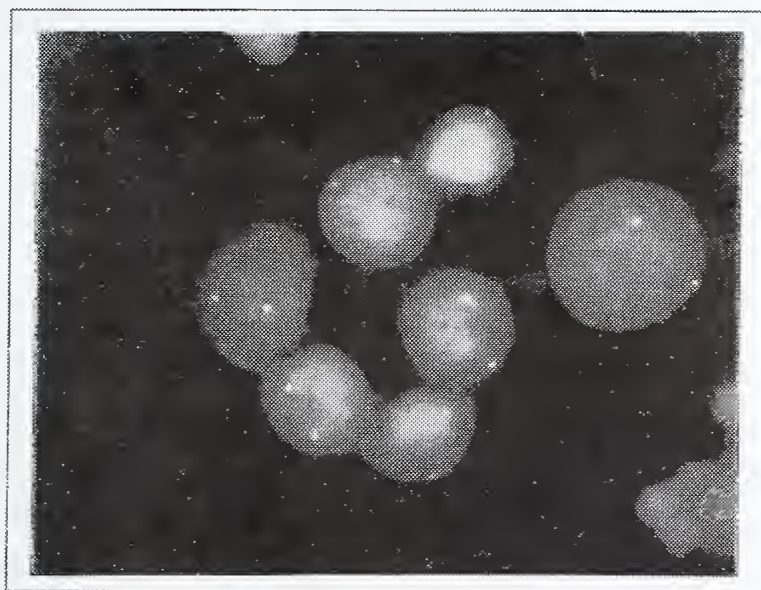
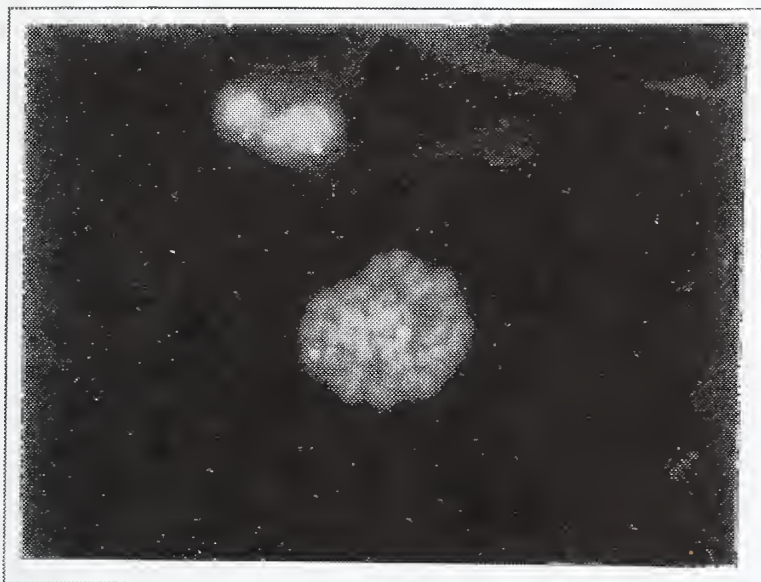


Figure 1b. FISH using a chromosome 9-specific classical-satellite probe (Oncor, Gaithersburg, MD), demonstrating two copies of chromosome 9.

MATERIALS AND METHODS

Bone marrow is the preferred tissue for culture in hematopoietic disorders.³ Harvesting of bone marrow for chromosomes was performed according to a modified protocol of the original peripheral blood method of Moorhead.⁴ GTG-banding was carried out according to the methods of Seabright⁵ and Sumner.⁶

For FISH, modifications of the procedures of clinicians^{3,7-13} as well as manufacturers' instructions (Oncor, Gaithersburg, MD; and Vysis, Downers Grove, IL) were followed.

For chromosome 8 and chromosome 9 centromere enumeration, a chromosome 8-specific α -satellite probe and a chromosome 9-specific classical-satellite probe, respectively, from Oncor were used.

RESULTS

Chromosomal analysis of 22 metaphases derived from an unstimulated culture of bone marrow revealed the modal number of chromosomes to be 47 per cell with a male sex constitution and an extra C-group chromosome. The initial cytogenetic diagnosis was 47,XY,+C. Unequivocal identification of the extra chromosome based on GTG-banding

(data not shown) was not possible because the preparation was suboptimal.

FISH was used as an adjunct to conventional cytogenetics in order to delineate the nature of the trisomy. FISH using a chromosome 8 α -satellite probe revealed three signals, whereas FISH using a chromosome 9 probe revealed only two signals. Thus, based on the results of GTG-banding and FISH, the cytogenetic results were established as 47,XY,+8,ish 8(D8Z1x3),9(D9Z1x2). Representative FISH results are given in Figure 1.

DISCUSSION

Trisomy 8 is one of the most frequent numerical chromosomal abnormalities found in cancer. In leukemia it is reported most frequently in myelodysplasia. The focus of the present report is the application of FISH for the detection of commonly encountered numerical chromosomal abnormalities such as this trisomy. Extended discussions of trisomy 8 have been provided elsewhere.^{1,3,14}

Conventional cytogenetic analysis is a highly informative test. Using GTG-banding the human genome can be examined in its entirety at a single glance. Culturing and harvesting of cells for conventional cytogenetic analysis are labor-intensive processes, requiring highly trained personnel. The harvesting protocol essentially entails the use of Colcemid to arrest the chromosomes in metaphase, a hypotonic treatment to improve chromosome spreading, and fixation using three parts of methanol to one part of acetic acid. After slides are prepared they undergo one of the banding protocols, such as GTG-banding. This is followed by karyotyping, whereby metaphase chromosomes are arranged according to shape, size and banding patterns. Thus, conventional cytogenetics requires dividing cells.

FISH is a relatively new technique that augments conventional cytogenetics in difficult cases where the exact nature of the chromosomal abnormality cannot be clearly defined. FISH may be able to unequivocally delineate the nature of the chromosome abnormality and serve as a valuable adjunct technique for diagnosing disease subtypes. In addition, FISH can be performed on nondividing cells, thus enabling an analysis of a larger sample. The ability to analyze large numbers of cells is significant because it permits

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the detection of low frequency abnormalities that are otherwise difficult to detect. For this reason, it may be very useful for detecting minimal residual disease. Additionally, FISH is rapid because it does not require special training for scoring. It also facilitates the correlation of cytogenetic findings with morphology, which is not possible with conventional cytogenetics because all nuclear details are lost in a

metaphase cell. When used as an adjunct, FISH offers benefits in both the study of malignant cells and in the management of patients with malignant disorders.

Recent advances in molecular technology have led to the development of newer techniques that combine the sensitivity and specificity of FISH with the global screening ability of conventional cytogenetics. Notably, spectral karyotyping, or SKY¹⁵, permits an examination of the entire genome in a single hybridization. However, because techniques such as comparative genomic hybridization, or CGH¹⁶ and SKY require specialized instrumentation and trained personnel, the exact roles that these new emerging technologies will play in the average clinical cytogenetic laboratory in the current climate of managed care and cost containment¹⁷ are yet to be determined. As with all new technologies, caution should be exercised; irreversible therapeutic decisions should not be based solely on the results of interphase (nuclear) FISH.

ACKNOWLEDGMENTS

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Point of View: New York's "Bell" Regulations Revisited

A Reminiscence: Teach One, Do One, See One

Joseph H. Friedman, MD

Michael Tobias' wonderful article¹ on the Bell laws of New York in the August issue of *Medicine & Health/Rhode Island* and the quote from Dr. Gouge, Director of Surgery at New York University, got me reminiscing about my own medical training in the pre-Bell era in New York City. A medical school friend, interning in general surgery at NYU, rotating through Bellevue, the city hospital in 1978, told me of an encounter in the emergency room with a complicated laceration. He called his senior resident, who listened to the description and responded, "Do a Z-plasty." "But I've never seen one," my friend responded. "Don't worry," was the response, "here's how you do it..." My friend described NYU general surgery teaching motto as, "Teach one, do one, see one." This neatly captured the unfortunate spirit of the times, August 24, 1978.

When I moved to Providence in 1982, I was impressed that the emergency rooms appeared to be run by attending level physicians. This was a new experience to me and even being a novice physician I realized that patients must be getting better care as a result. As a medical intern at Mt. Sinai Hospital in New York (1978-79), I worked under a senior resident until midnight. The intern was alone, covering the pediatric and adult ER after midnight, with the resident sleeping in a nearby on-call room, readily available. During the day a senior resident oversaw my care. I vividly recall being on a ward, having recently completed the ER rotation, receiving a call from an attending physician who wanted me to know how dangerous it was for me to have sent home his diabetic patient with a urinary infection and a fever of 101.5 degrees. I of course took co-responsibility but explained that my supervising resident made the decision. In fact, we were less at fault than the system that turned over such serious responsibilities to partly trained physicians, to "sink or swim," as Michael Tobias puts it, without supervision. When I was a resident at Columbia Presbyterian Medical Center, the medical and surgical ERs were run by housestaff. Attendings were rarely seen. And even on the consult service in my discipline, neurology, patients needing neurology consultations were frequently not seen by attending level physicians. Toward 5 p.m. it was common for the attending to say, "Is there anyone who NEEDS to be seen today?"

In a profession whose motto is "First do no harm," the idea of learning at the patient's expense is impossible to justify. Certainly we have learned and continue to learn by

practicing on real people. However we learn best through supervision, reportedly the heart of the Bell regulations. The physician-teachers who argue against the Bell regulations have an economic point but certainly not a moral or educational one. The ones who rail the hardest are the ones least likely to let their children or family be cared for by the unsupervised house officer.

Some of the New York State Bell regulations mandating supervision have come into effect nationally through health care financing "reforms." Supervision is now required for reimbursement by Medicare for services rendered by housestaff. Interestingly, the doctors who thought supervision was not very important, who sanctioned surgery by residents with "supervision" provided from out of state (countersigning backdated notes) have paved the way to mandated supervision. They now have to document their presence at the time of delivery of "key"

evaluations and services.

Michael Tobias neglected to mention the unique aspect of the Libby Zion case, which culminated in the Bell regulations. It was not a malpractice suit. It was a criminal suit. And although it named a house officer, it aimed at the whole system.

We can argue about how many hours a young adult can work and still learn and provide relatively effective care, but there is no arguing that medical education requires harming patients. Perhaps we should be developing "baby Bells."

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Prevalence of Asthma in Rhode Island

Jay S. Buechner, PhD and Hanna Kim, PhD

Asthma is among the most commonly reported chronic conditions in the United States, and its prevalence has been increasing in recent years.¹ In 1994, asthma ranked seventh nationally among chronic conditions reported by persons of all ages, after chronic sinusitis, arthritis, hypertension, allergic rhinitis without asthma, hearing impairments, and deformity or orthopedic impairment of the back.² Even more critical, it was also the most commonly reported chronic condition among children under 18 years. Nationally, it affects an estimated 14.5 million persons and in Rhode Island an estimated 71,000. This report presents survey data describing the prevalence of asthma among Rhode Island residents and the subsequent limitation of activities.

Methods

In 1996, the telephone-based Rhode Island Health Interview Survey obtained information on all members of participating households, including demographic, social, and economic characteristics, coverage for health care costs, general and specific measures of health status, and other items. In total, 2,580 households with 6,583 persons were

included in the survey. For each person, it was determined whether he or she suffered from asthma. For persons reported as having asthma, it was determined whether or not they had been told this by a physician. Prevalence data for Rhode Island are based on all reported cases for comparability with national data.

In addition, the survey collected information on activity limitations for all persons in the participating households. This information was converted into a four-level hierarchical scale, as follows:

- No Major Activity: Persons who were unable to perform their age-appropriate major activity, e.g., attending school, working at a job or business, keeping house.
- Limited Major Activity: Persons who were limited in the kind or amount of their major activity they could perform.
- Other Limitation: Persons who were limited in any way in the performance of activities other than their major activity.
- No Limitation: All persons not in the above categories.

The survey collected information on limitations of activity that resulted from "any impairment or health problem" and did not link the collected information to specific health conditions.

Results

In 1996, the estimated prevalence of asthma in Rhode Island was 71.5 cases per 1,000 residents; this rate was 27% higher than the most recent national rate reported and 21% higher than the regional rate for nine Northeastern states.² (Figure 1) Of persons reporting having asthma in the survey, 96% had been diagnosed by a physician. Nationally, the prevalence of asthma increased from 30.7 cases per 1,000 in 1980 to 56.1 cases per

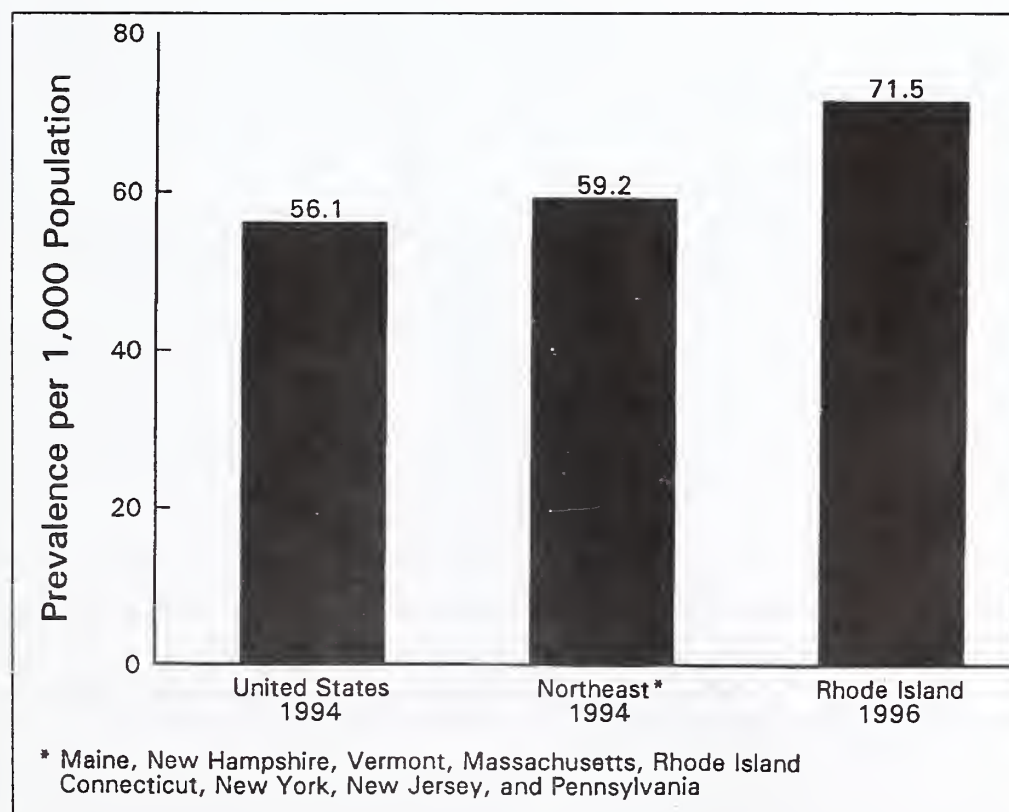


Figure 1. Prevalence of Asthma, United States (1994), Northeast (1994), and Rhode Island (1996).

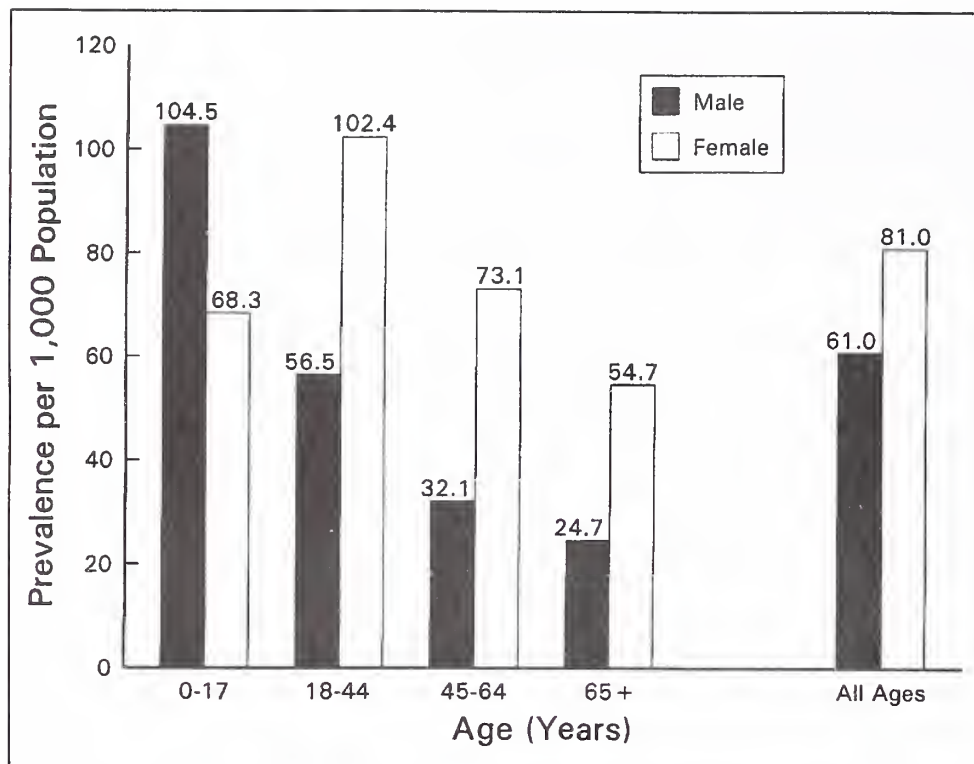


Figure 2. Prevalence of Asthma, by Age and Sex, Rhode Island, 1996.

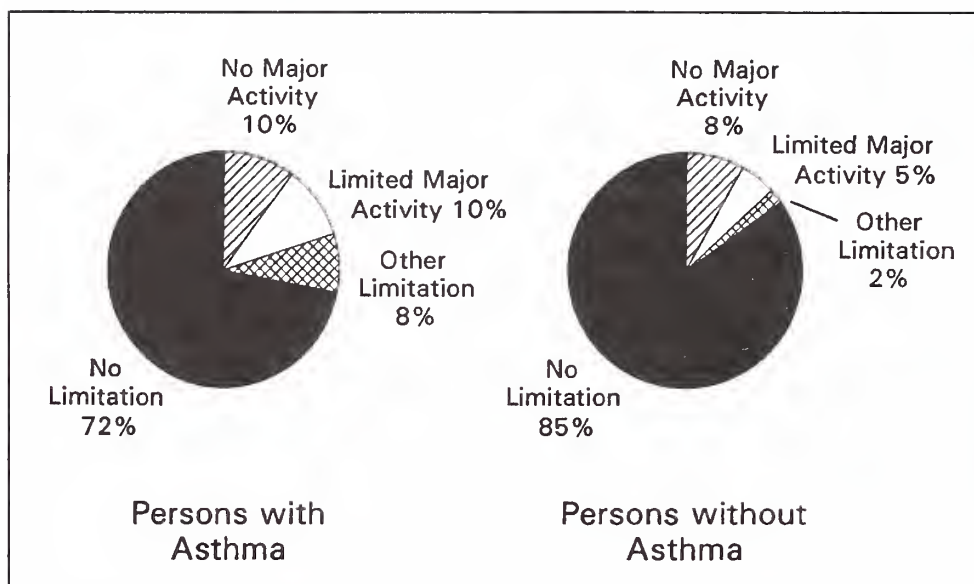


Figure 3. Distribution of Activity Limitation, by Asthma Status, Rhode Island, 1996.

1,000 in 1994, or by 83%.¹

Asthma rates were generally higher among younger Rhode Islanders (under age 45), and higher among females (81.0 cases per 1,000) than among males (61.0). For males, the greatest prevalence occurred among children; for females, it occurred during the child-bearing years. (Figure 2). Black and Asian Rhode Islanders showed elevated prevalence rates (13% and 12% above the state average, respectively), and White Hispanic residents had lower prevalence than average (13% lower). Residents of the state's urban areas, including Providence, Pawtucket, Central Falls, Newport, and Woonsocket, also showed slightly elevated prevalence (81.3 cases per 1,000) compared to residents of other areas (67.3 cases).

Asthma sufferers were approximately twice as likely as other survey respondents to report being limited in their activities. (Figure 3) The difference between the two groups was smallest at the highest level of activity limitation, no major activity, and was highest for limitations affecting activities other than the major activity. Overall, approximately 28% of persons with asthma reported an activity limitation, compared with 15% of persons without asthma. Nationally, approximately 22% of persons with asthma experienced some limitation in their major activity in 1994, compared with 20% of Rhode Island's population with asthma.¹

Discussion

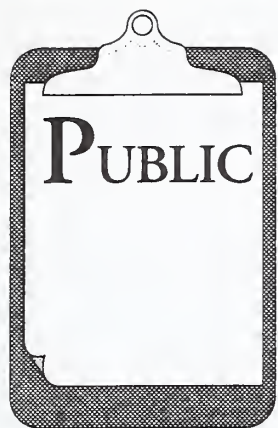
Asthma is an increasingly common chronic condition that results in limitations of activity for more than one in four Rhode Islanders who have it. It is the most common chronic condition seen among children, and it is more common among Black, Asian, and urban residents in the state. The costs of medical care for asthma are substantial, not only for management in ambulatory settings, but also for treatment of acute episodes in hospital emergency rooms and inpatient settings.³ A first step toward increased coordination between prevention and treatment efforts is improved information on the prevalence, treatment, and outcomes of asthma in our population, as well as the ability to monitor trends in these measures over time

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Jay S. Buechner, PhD, is Chief, Office of Health Statistics, and Assistant Professor of Community Health, Brown University School of Medicine.

Hanna Kim, PhD, is a Health Data Analyst in the Office of Health Statistics.



Tools Available to Facilitate Consumer Choice in Health Coverage

Robert Marshall II, PhD, and Richard Bolig, MS

CONSUMER SAFEGUARDS

Rhode Island has one of the strongest laws in the country to inform consumers about health plan choices and to preserve consumers' rights regarding their health plan. It began with a "Special Legislative Commission to Study Managed Care Plans and Their Impact on Patients' Ability to Make Choices Related to their Health Care Providers." This Commission met for two years and produced the Health Care Accessibility and Quality Assurance Act of 1996. Its provisions apply to all managed care health plans in the state, both publicly and privately funded.

LEGAL REQUIREMENTS

The law makes the Health Department responsible for the certification of health plans every two years, the monitoring of the accessibility and quality of health services, and the investigation of complaints. Under what is perhaps the law's most far-reaching requirement, health plans must give their members information that explains how their coverage works in a format that permits easy comparison of alternative plans. To accomplish this, the Health Department and plan representatives created two booklets designed to provide health plan consumers and potential consumers with the information they need to make sound choices.

TOOLS FOR COMPARISON

The booklets were designed to be streamlined, non-technical, and succinct. They are distributed to subscribers by their plans. They are also available directly from the Health Department at 222-6015.

To serve their purpose, it is essential that they be given visibility, that patients be encouraged to read them and use them, and that providers use them as tools for answering questions and providing explanations.

The Consumer's Right to Know About Health Plans in Rhode Island is an 8-page booklet on an individual plan's policies, procedures, and services, including information on:

- How prior authorization is handled
- How emergency services are handled
- How the plan pays providers
- What out-of-pocket expenses apply
- What limitations and restrictions apply
- Whether services by non-participating providers are covered

The Consumer's Guide to Health Plans in Rhode Island is a 16-page booklet on requirements for all health plans in Rhode Island, distributed by every plan to every subscriber, including information on:

- How to recognize differences between health plans
- What health benefits are mandated by RI law
- What professional service options and other requirements are mandated by RI law

The *Consumer's Guide* contains a glossary giving standardized definitions of plan terms.

HOW CAN HEALTH CARE PROVIDERS HELP?

Consumers are more likely to derive benefits from the two booklets if providers demonstrate a familiarity with them and endorse their use. Providers are welcome to get copies of the booklets, as well as any additional information needed about their content or the health plan certification process, from the Health Department's Office of Health Services Regulation, at 222-6015.

Robert Marshall, PhD, is Assistant Director for Community Affairs, Rhode Island Department of Health.

Richard Bolig, MS, is Public Information Officer, Rhode Island Department of Health.

Consumer's Guide to Health Plans in Rhode Island 1998

*A Publication of the
Rhode Island Department of Health
in Cooperation with
the Health Plans of Rhode Island*

*Safe and Healthy Lives
in Safe and Healthy Communities*

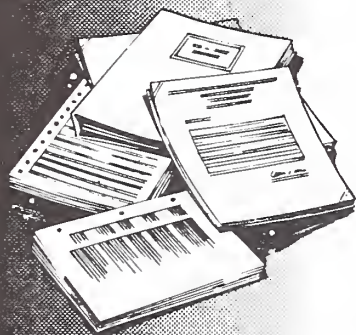
Consumer's Right to Know About Health Plans in Rhode Island

Consumer Disclosure

*Safe and Healthy Lives
in Safe and Healthy Communities*

This pamphlet explains what the law requires, and what consumers can expect from every health plan in Rhode Island.

For consumers with a health plan already, this pamphlet tells what their particular plan provides.



CLINICAL TRIALS DIRECTORY

A Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging, Study for the Safety, Tolerability and Efficacy of S1B-1508Y in Parkinson Disease Patients who are Requiring but Not Receiving Dopaminergic Therapy

Sponsor: S1B1A Neurosciences and the Parkinson Study Group

Purpose: Joseph Friedman, MD, is conducting this trial to treat patients with early Parkinson's Disease. Patients will be treated with varying doses of a nicotinic agonist looking at both symptomatic motor effect and memory enhancement.

Patients Recruited: People with Parkinson's Disease not receiving Dopaminergic drugs. MMSE must be >24. May be on Eldepryl. No agonists, amantadine, antidepressants, or neuroleptics.

Intervention: varying doses of S1B-1508Y vs. placebo

Duration of study: 5 weeks

Phase: IIa

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

A Multi-Center, Placebo-Controlled Trial of Melatonin for Sleep Disturbance in Alzheimer's Disease

Sponsor: Alzheimer's Disease Cooperative Study

Purpose: Brian Ott, MD, is conducting this trial to treat Alzheimer's Disease patients who experience sleep disturbances associated with Alzheimer's Disease. Two doses of melatonin will be used to treat sleep disturbances in order to lessen the burden on caregivers and family members.

Patients Recruited: Anyone 55 years or older with a diagnosis of probable Alzheimer's Disease experiencing sleep disturbances.

Intervention: Two doses of Melatonin vs. placebo

Duration of study: 12 weeks

Phase: III

Site: Alzheimer's Disease & Memory Disorder Clinic, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Michael Pimental, MA, phone (401) 729-3752

Martin B. Keller, MD
Chairman, Department of Psychiatry and Human Behavior
Brown University School of Medicine *announces. . . .*

Third Annual Research Symposium on Mental Health Sciences

Keynote Speaker

Enoch Gordis, MD

Director, National Institute on Alcohol Abuse and Alcoholism

Featured Faculty Presenters

**Henrietta Leonard, MD ♦ Richard Longabaugh, PhD
Rena Wing, PhD**

December 1, 1998 ♦ 12:30 pm-5:15 pm
Ray Conference Center ♦ Butler Hospital Campus

Registration is free. Buffet will follow.
Please contact Janet Brucato at 401.455.6433 for more information.

Medicine & Health/ Rhode Island is pleased to launch this Directory. In Rhode Island, many researchers—hospital-based and community-based—are conducting clinical trials; but the channels of communication are not optimal. We intend this Directory of Clinical Trials to serve as an information clearinghouse for ongoing trials in the state. If you would like to list a trial, please contact:
Joan Retsinas
Managing Editor
phone/fax: (401) 272-0422
e-mail: JRetsinas@aol.com.

Earlier vs. Later Levo-dopa in Parkinson's Disease (ELLDOPA)

Sponsor: NIH and the Parkinson Study Group

Purpose: Joseph Friedman, MD, is conducting this trial to compare the effect of early or late treatment of Parkinson's Disease with L-Dopa to answer the question of whether L-Dopa slows or hastens the progression of Parkinson's Disease.

Patients Recruited: Patients must be 30 years or older, must be diagnosed with Parkinson's Disease within the last 2 years. No eldepryl, L-DOPA, amantadine, anticholinergics, antihistamines, antidepressants, or benzodiazepines for previous 30 days.

Intervention: varying doses of Carbidopa/Levodopa vs. placebo

Duration of study: 9 months

Site: Movement Disorder Unit, Memorial Hospital of RI,
111 Brewster St, Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

For HIV Infection: DMP 266-006: A Phase III, Multicenter, Randomized, Open-Label Study to Compare Antiretroviral Activity and Tolerability of Three Different Combination Regimens in HIV-Infected Patients

Sponsor: DuPont Pharmaceuticals

Purpose: This trial evaluates three highly effective combinations (DMP266 + Indinavir; DMP266+ Zidovueine + Lamivudine; Indinavir + Zidovudine + Lamivudine), including a promising drug called DMP266 (efavirenz, Sustiva). Karen Tashima, MD, is the principal investigator.

Patients Recruited: HIV-infected adults who have taken few or no antiretroviral medications.

Intervention: three combinations of drugs (DMP266 + Indinavir; DMP266+ Zidovueine + Lamivudine; Indinavir + Zidovudine + Lamivudine), including DMP266 (efavirenz, Sustiva).

Compensation: Patients receive compensation.

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Timothy Bose, phone: (401) 793-4971

For HIV Infection: An Open-Label, Two-Center Trial to Evaluate the Efficacy and Safety of Quadruple Chemotherapy (Epivir, 1592U89, and 141W94 with Indinavir) in Subjects Newly Infected with HIV-1

Purpose: Conducted with the Aaron Diamond AIDS Research Center, this trial is for patients who are in the seroconversion period when circulating virus is at very high levels. The potential benefit of treating with four antiretroviral medications at this stage of HIV infection will be investigated. Karen Tashima, MD, is the principal investigator.

Patients Recruited: Patients in the seroconversion period (prior to the development of HIV antibodies)

Intervention: Epivir, 1592U89, and 141W94 with Indinavir

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Joan Gormley, RN, phone: (401) 793-4398

HIV: Expanded Access Programs

Intervention: Efavirenz (a non-nucleoside reverse transcriptase inhibitor) and abacavir (nucleoside reverse transcriptase inhibitor) are available in expanded access programs. Karen Tashima, MD, is the principal investigator.

Site: The Immunology Center, The Miriam Hospital, Summit St, Providence, RI 02906.

Contact: Joan Gormley, RN, phone: (401) 793-4398

Zyban Collaborative Study

Sponsor: National Institutes of Health; The Miriam Hospital, a Lifespan partner; and Butler Hospital, a Care New England partner

Purpose: The Zyban Collaborative Study is investigating the effects of the combination of Zyban, an FDA-approved medication for smoking cessation, and group counseling to assist with quitting smoking. It is anticipated that this combination of treatments will be particularly effective in the increasing number of "hard core" smokers.

Principal Investigator: Raymond Niaura, PhD, and Richard Brown, PhD

Patients recruited: This free research study is open to cigarette smokers who are at least 18 years old, in good health, smoke 10 or more cigarettes a day, and want to quit smoking.

Intervention: Participants have a 50/50 chance of being assigned the active medication Zyban versus a placebo; they will receive a free medical screening and 12 group counseling sessions.

Duration of study: Participation in the study will last up to one year and will include 12 group visits during a 3-month treatment period, and 3 follow-up visits at 2, 6, and 12 months after the start of treatment.

Phase: Subject recruitment will continue for approximately two-and-a-half years. Participant screenings are scheduled on a continuous basis; new groups begin every seven weeks. Evening groups are available.

Site(s): The Miriam Hospital and Butler Hospital

Compensation: Participants will receive up to \$140 for completing all of the questionnaires and follow-up assessments after treatment ends. Abstinence from smoking is not required in order to be reimbursed.

Contact: The Lifespan Health Connection for further information and screening for participation in the study, phone (401) 444-4800

Dr. Elizabeth Lloyd with specific questions. phone (401) 793-3714,

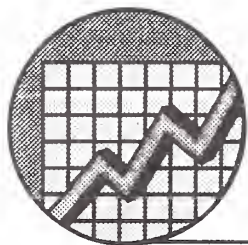
e-mail: ELloyd@Lifespan.org

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	April 1998	12 Months Ending with April 1998	
	Number	Number	Rates
Live Births	962	13,306	13.4*
Deaths	774	9,914	10.0*
Infant Deaths	(13)	(100)	7.5#
Neonatal deaths	(11)	(80)	6.0#
Marriages	405	7,683	7.8*
Divorces	219	3,221	3.3*
Induced Terminations	354	5,126	385.2#
Spontaneous Fetal Deaths	34	921	69.2#
Under 20 weeks gestation	(24)	(854)	64.2#
20+ weeks gestation	(10)	(67)	5.0#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	October 1997	12 Months Ending with October 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	263	3,332	336.5	3,799.0
Malignant Neoplasms	229	2,497	252.2	6,957.5
Cerebrovascular Diseases	53	705	71.2	830.0
Injuries (Accident/Suicide/Homicide)	28	336	33.9	6,535.5**
COPD	46	464	46.9	320.0***

**Excludes two deaths of unknown age

***Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

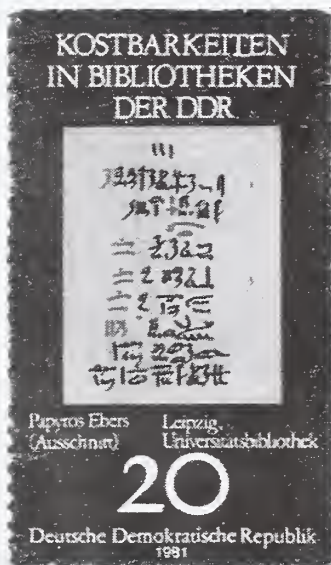
Philately in Medicine

John Tierney

☞ The Beginnings of Medicine ☞

The oldest medical deity of Egypt was Toth, a male figure with the head of an ibis, considered the source of all knowledge and the god of education and art. He was recognized as the Creator of Letters. His *Sacred Book*, consisting of 42 volumes, included 6 volumes of medical knowledge. [Egypt, 1925, #105]

Since early civilizations believed sickness was caused by evil spirits invading the body, the witch doctor emerged to drive them out of the body. [Angola, 1958, #410] (Sida means AIDS).



Imhotep, which means "he who cometh in peace," was an Egyptian physician and the first well-known doctor in medical history. He died about 2850 B.C. and was worshipped as the god of medicine.

The Papyrus Ebers [East Germany, 1986, #2207] was written around 1550 B.C. and was found at Luxor. In 1873, George Ebers (1837-1898) bought it from Edwin Smith, an American scholar. In 1875, its copied version was opened to the public and is stored in the library of Leipzig University (Karl Marx University). It is an appointed cultural property as a complete medical book. It was translated by H. Joachim in 1890 and retranslated by B. Ebbelt in 1937.



CORRESPONDENCE
John Tierney
111 Amherst Avenue
Pawtucket, RI 02860

NINETY YEARS AGO

❧ [OCTOBER, 1908] ❧

A summary of the proceedings of the American Proctologic Society is published. Prior to the scientific component of the program, the membership collectively reflected upon the recent advances of their specialty noting that proctology was now a standard subject in the curriculum of virtually every school of medicine in the United States. The papers presented included studies on the treatment of choice for rectal stricture [syphilis, according to the author, is one of its major causes]; the clinical course, complications and therapy for interstinal amoebiasis [all of the reported patients ate locally grown vegetables washed with water from shallow wells]; galvanic electricity in the treatment of hemorrhoids and fistulas; profound anemia

due to internal hemorrhoidal bleeding; spontaneous intestinal anastomosis; carcinoma of the rectum with comparative results following different operative procedures; a case report of a woman who had swallowed her false teeth. By means of skiagraphy [an earlier term for X-rays] it was located in the lower sigmoid; and under sedation the prosthesis was extracted by a long forceps via an inserted sigmoidoscope.

The *Journal* publishes a notice from the Treasury Department announcing examinations for the tenured post of Assistant Surgeon in the Bureau of Public Health. Starting salary is listed as \$1,600 per year with furnished quarters.

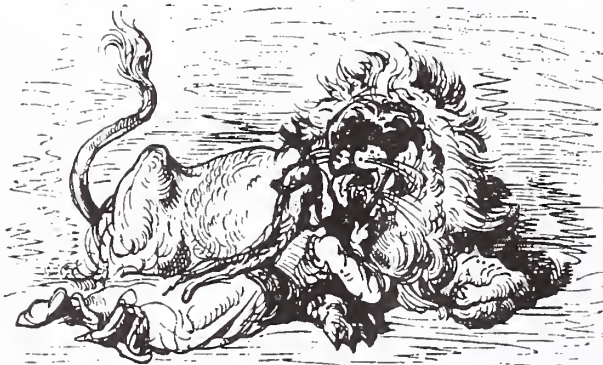
Charles V. Chapin, MD, reports on the state of health in Providence during the summer of 1908. While diarrheal disease remains the chief cause of death [97 deaths in July alone] its frequency has clearly diminished. There were 51 deaths from tuberculosis, 11 deaths from diphtheria, three deaths from typhoid fever and four deaths from meningitis.

FIFTY YEARS AGO

❧ [OCTOBER, 1948] ❧

William Brown, MD, from Tufts Medical School discusses the more effective procedures in the treatment of injured hands particularly when prevention of crippling deformities must be considered. A correct anatomic diagnosis remains the first essential step. The author then describes, in detail, the technical preparation for operative intervention, the personnel and instruments needed, the type of examination of the wound prior to rigorous cleaning, the debridement process, technics for approximating the viable ends of the divided structures, and finally, the operative dressing. The author constantly stresses the need for painstaking technic and cleanliness.

A group of seven cases of pneumonia not responsive to penicillin is analyzed by Morgan Cutts, MD. Autopsy examination revealed an empyema in the first case; a probable tuberculous pneumonia in the third case; a purulent pericarditis in yet another case; and at least one of the cases showing histologic changes compatible with a pneumonitis of viral origin.



TWENTY FIVE YEARS AGO

❧ [OCTOBER, 1973] ❧

Seebert Goldowsky, MD, offers a comprehensive plan for a coordinated peer review program throughout the state of Rhode Island. Part of the plan envisions the state Medical Society creating a Professional Standards Review Organization, a coordination of the three major data bases in the state and the active participation of the Hospital Association of Rhode Island.

Frank Davidoff, MD, summarizes the uses, pharmacology, modes of action and resulting complications of the major oral hypoglycemic agents.

Electrocoagulation in the treatment of cancer of the rectum is described and compared with results obtained by conventional abdominoperineal resection. The authors are John Madden, MD, and Souhel Kandalaft, MD.

A.A. Savastano, MD, Paul Poirier, MD, and Joseph Izzi, MD, describe the use of double contrast arthrography, particularly in cases of suspected medial meniscus disease in the knee.

The four year curriculum of the new medical school at Brown University is summarized.



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Diabetes Mellitus Type 2: A CME Issue



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The Epidemiology of El Niño

"He that observeth the wind," declares Ecclesiastes, "shall not sow; and he that regardeth the clouds shall not reap." Perhaps; but most early cultures saw substantial benefit in relentlessly studying the winds since they perceived atmospheric change to be a major cause of disease; and in these winds, they also believed, were to be found hints of their destiny.

Over two millenia ago the great physician of the island of Cos, Hippocrates, taught that human illness was caused by secular phenomena which resulted in an imbalance within the constituents of the body; and that these systemic alterations, in turn, were governed by such natural events as atmospheric and climatic variation.

The Hippocratic text called *"Air, Waters, Places"* begins with these instructive words: "Whoever wishes to pursue properly the science of medicine must proceed thus. First, he ought to consider what effects each season of the year can produce; for the seasons are not all alike, but differ widely both in themselves and at their changes. The next point is the hot winds and the cold, especially those that are universal, but also those that are peculiar to each particular region."

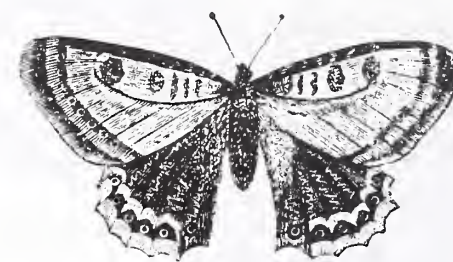
And for the next few millennia western medicine believed fervently in the capacity of the winds to transport both distress and sickness. During the Middle Ages, southern England was said to suffer greatly from malaria which was authoritatively ascribed to noxious, putrefactive mists emanating from the fenlike swamps of Suffolk. Fifteenth Century clerical chroniclers took careful note of weather changes such as frosts and great winds and regularly associated them with epidemic intervals. The years between 1433 and 1440, for example, were years of much bubonic plague but also a time of blustery, damp winds and cold. Indeed medieval winds were more than mere westerly or northerly winds; they frequently were classified also as portentous, idle, evil, kindly, cruel, faithless, benevolent, bountiful or even ill [in the words of Heywood, "an ill wind that bloweth no man to good."]

Long before the indictment of bacteria and viruses as the agents of air-borne contagion, winds - especially those associated with mists and fog - were deemed responsible for much of human pestilential disease. A major school of medical belief contended that ill-defined noxious substances were carried by tainted winds, called miasma [from a Greek word meaning stained or polluted.] Relief, it was contended, might be sought by moving to hilltops free of mist or to drier, warmer climates.

In a world innocent of any notion of the underlying nature of infectious disease, the miasmatic theory of illness easily prevailed. Only when causative agents were indisputably linked with diseases such as cholera, tuberculosis and plague did the miasmatic theory of disease finally retreat. Yet in 1876, a decade after the germ theory of disease became widely accepted, a major English textbook of medicine still asserted: "The miasm may be carried by the wind and atmospheric currents beyond the limits of the area in which it is produced." It would be a while before mists and changing winds would finally become mere climatic elements rather than emissaries of disease.

Every five years or so, the chilly but nutrient-rich Pacific Humboldt current off the western coast of South America is displaced by a warmer, but nutrient-poor equatorial current producing a sharp drop in eastern Pacific ocean fishing yields. This cyclic deviation in the distribution of oceanic currents also generates dramatic changes in wind patterns, temperatures and precipitation over much of South America. Typically, these climatic anomalies begin to occur about Christmas time and hence they are called El Niño [Spanish for Christ child.] Since 1984 there have been four recorded El Niño episodes.

The El Niño phenomena result in dramatic modification in climatic conditions, indisputably in South America and possibly elsewhere. There has even been speculation that El Niño is also correlated, in some fashion, with global warming; and perhaps, as a vestigial hint of the mori-



bund miasmatic theory, even some changes in the incidence rates of certain infectious diseases.

In recent years, the Pan-American Health Organization [a branch of the World Health Organization] has heightened its South American surveillance of such diseases as malaria, dengue [a viral disease carried by the mosquito], and cholera. During the past year, they have recorded over 200,000 cases of acute malaria in Peru alone, this sobering increase coinciding closely with the increased rainfalls and resultant humidity which favor mosquito propagation. The excessive west coastal rainfall of South America, associated with El Niño, has resulted in local flooding and therefore a predictable rise in cholera [a water-borne infectious disease historically correlated with flood-created sewage contamination of the water supply.]

In general during this past year, El Niño has caused flooding in some South American regions, drought in other regions and, in general, a significant disruption of public utilities and public health services all contributing materially to the local deterioration of health.

A recent west coast United States outbreak of human dysentery, caused by *Vibrio parahaemolyticus*, has been blamed on the warming of the oceans near the west coast oyster beds, an indirect effect of El Niño. This demonstrated warming has created a more favorable environment for the growth of the *Vibrio* organisms in the vulnerable oysters.

The world is no longer a quiet place with distant sites known only through legend or belated news reports. The winds that blow over the southeastern Pacific may affect the health of an elderly widow in a Peruvian village, the income of a Chilean fisherman, the edibility of fresh oysters from the Oregon coast and, perhaps in subtle ways, even the well-being of a child in Westerly, Rhode Island. Truly, the world is shrinking. Yesterday's disease on a distant continent may be an ominous neighborhood problem before tomorrow's sundown.

— Stanley M. Aronson, MD

Diabetes Mellitus Type 2: A CME Issue

Introduction

Edward Westrick, MD, MS

Diabetes mellitus (DM) is a common, complex, chronic disease with acute and long-term complications that are preventable. This issue of *Health & Medicine/Rhode Island* focuses on those complications. Readers can earn Category 1 Continuing Medical Education (CME) credit from Brown University. The material is primarily intended for primary care physicians who care for patients with type 2 DM. The articles are organized to address four primary educational objectives. Participants should be able to (1) explain strategies for the prevention of microvascular and macrovascular complications in type 2 DM; (2) recognize new legislation, programs, and projects at the national and state levels related to diabetes care; (3) identify barriers to diabetes self-management; and (4) develop a system for diabetes care using existing multidisciplinary resources in the health care community.

Strategies for the prevention of complications are addressed in the articles on: retinopathy, nephropathy, lower extremity amputation prevention, glycemic control, and cardiovascular disease risk factors.

Drs. Figueroa and Richman make a compelling case that blindness due to diabetic retinopathy can be prevented by identifying the disease in its early, treatable stages and referring patients for therapy. Identification of early disease is best accomplished by regular annual dilated funduscopic examination by an eye doctor even before patients become symptomatic.

Drs. Clement and Cottiero summarize the background material on diabetic nephropathy, relevant to primary care physicians. They suggest a screening strategy to identify patients with early disease and highlight the role of ACE inhibitors in preventing progression of disease.

Drs. Quevedo and Werber provide different perspectives on diabetic foot disease. Dr. Quevedo offers a simple screening tool for identifying early neuropathy using a monofilament test. A monofilament is provided for your use. Dr. Werber shares the podiatrist's approach to diabetic foot disease so that you have a more complete picture of what happens after you

make the referral.

Dr. Quevedo and I summarize the key points on the role of glycemic control in preventing microvascular complications. This summary includes our preliminary evaluations of the recently reported United Kingdom Prospective Diabetes Study (UKPDS). This landmark series of studies essentially extends the finding of the Diabetes Complications and Control Trial (DCCT) from type 1 DM to type 2 DM.

Dr. Hennessey and I provide a model for cardiovascular disease risk stratification and a method for identifying modifiable risk factors. Obesity, hypertension, dyslipidemia, and smoking are discussed. Implications of the UKPDS are included in this discussion.

Quality of care in diabetes has attracted significant attention at the national and local levels. New legislation mandates payment for services and supplies. Measurement of quality and the recognition of superior performance are part of new national programs. Quality improvement projects are being organized at the national level and implemented locally. Goldman, Lindenmayer, and I summarize the major national and local legislation, programs and projects.

It is becoming increasingly clear that diabetes requires life-long self-management, which is demanding both for patients to execute and for providers to teach and encourage. Dr. Ruggiero's article offers an approach to dealing with the common barriers to self-management.

In a case discussion, Dr. Maxim illustrates his systematic approach to these complex problems, using the multidisciplinary resources in the community. The contact list should facilitate your interaction with these resources.

This issue of *Health & Medicine/Rhode Island* will test the feasibility of offering Category 1 CME activities through the journal. After reading the articles, answer the quiz at the end. If you answer more than 70% of the questions correctly, you will receive 2 hours of Category 1 CME from the ACCME accredited sponsor, Brown University. We are interested in your opinions about using this journal for future CME activities.

I want to thank the Lower Extremity Amputation Prevention (LEAP) Program for providing the monofilaments. Robert Rolfsen, Director of the program, can be reached at 504-642-4714. My thanks to the planning committee: Charles Kahn, MD, Ray Maxim, MD, Harold Woodcome, Jr., MD, Joann Lindenmayer, DVM, MPH, Dona Goldman, RN, MPH, Judith Bell, MPH, Barbara Niekerk, MEd, and Marcia Petrillo, MA. And special thanks to the authors for dedicating their valuable time and efforts.

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Diabetic Retinopathy

Francis X. Figueroa, MD, and Stephen Richman, MD

Diabetic retinopathy is the leading cause of blindness in the United States in patients under the age of 65 and accounts for at least 12% of new cases of blindness each year. An estimated 12 million Americans have diabetes, and studies have shown that 25% of them have some form of retinopathy. Previously considered untreatable, diabetic retinopathy and blindness were predictable results.

Over the past three decades, the use of lasers by ophthalmologists has dramatically changed that prognosis. Today there is a growing optimism that blindness due to diabetes can be eliminated. The key to preventing blindness is early diagnosis and appropriately applied laser treatment. Because diabetic retinopathy is often asymptomatic in its most treatable stages, its early detection through regularly scheduled ocular examinations becomes critical.

The pathology of diabetic retinopathy is thought to be secondary to the effects of elevated blood sugar on retinal vessels. The main cause of visual loss in this disease is edema of the macula due to leaking capillaries (diabetic microaneurysms). Visual loss can also be caused by intraocular bleeding or retinal detachment due to the development of neovascularization. These new vessels are the result of widespread retinal ischemia resulting from capillary drop-out and retinal arteriolar occlusions. The microvascular abnormalities of leakage and closure have been related to hyperglycemia but the biochemical mechanism is unknown. The only proven medical treatment to arrest the progression of diabetic retinopathy is good glycemic control. The lower the glycosylated hemoglobin level, the less likely patients will develop diabetic retinopathy. In patients who already have diabetic retinopathy, lowering the glycosylated hemoglobin level appears to slow the progression of the disease.

Dramatic strides in controlling diabetic retinopathy have been made through the effective use of scatter and focal laser techniques. Two nationwide randomized clinical trials have largely determined the strategies for appropriate clinical management of patients with diabetic retinopathy. In 1976, the National Eye Institute conducted the first ever national, multicenter, prospective, randomized, double-masked, Diabetic Retinopathy Study. Data from that study demonstrated a 50% reduction in the risk of severe visual loss in patients with severe proliferative diabetic retinopathy when laser scatter photocoagulation was applied. Beginning in 1980, again under the guidance of the National Eye Institute, 22 clinical centers nationwide began the Early Treatment Diabetic Retinopathy Study (ETDRS). Enrolling almost 4000 patients, the ETDRS evaluated photocoagulation in patients with mild to severe nonproliferative "background" diabetic retinopathy or early proliferative retinopathy. The study data demonstrated that focal rather than scatter photocoagulation was effective in treating eyes with central macular edema, or moderate nonproliferative disease, and twice as many untreated patients lost vision compared to treated patients with clinically significant macular edema.

Because diabetic retinopathy is often asymptomatic in its most treatable stages, its early detection through regularly scheduled ocular examinations becomes critical.



Abbreviations Used:

ETDRS Early Treatment Diabetic Retinopathy Study

Because diabetic retinopathy is usually asymptomatic in its earliest, most treatable stages, the emphasis must be on early identification, careful follow-up and timely laser photocoagulation. Strict guidelines have been established for the ocular care of people with diabetes. Patients with Type 2 diabetes should have a complete eye exam including dilated fundus evaluation at the time of diagnosis. If no retinopathy is present, patients should be followed yearly at a minimum. Associated medical problems present a significant risk for development and progression of diabetic retinopathy. These factors include pregnancy, hypertension, chronic hyperglycemia, renal disease and hyperlipidemia. Patients with these conditions may require more frequent monitoring.

The ophthalmic community is well aware of the availability of the technology and the recommended criteria and protocols for its application and the treatment of diabetic retinopathy. However, according to a recent study of HMO-enrolled diabetic patients, almost half of the known diabetic population in Rhode Island has not had a dilated ophthalmic examination. If the medical community is to fully realize the potential for saving eye sight in people with diabetes, it is essential that physicians responsible for the care of diabetic patients recognize the need for early diagnosis and treatment of diabetic retinopathy. Only with an effective partnership between the primary care physician and the ophthalmologist can the optimistic goal of preventing blindness from diabetic retinopathy be reached.

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Glycemic Control in Type 2 Diabetes Mellitus

Stephen F. Quevedo, MD, FACP, and Edward Westrick, MD, MS

Glycemic control has become a major goal in the management of diabetes mellitus. In this article we review the concepts of glycemic goals, hypoglycemic therapies (both pharmacologic and non-pharmacologic), and glycemic monitoring.

Improvement in glycemic control clearly reduces the risks of diabetic retinopathy, nephropathy, and neuropathy in type 1 diabetes mellitus.¹ There is increasing evidence that glycemic control has similar benefits in patients with type 2 diabetes mellitus. The benefits include both delay in onset and slowing of progression of these complications. The recently concluded, landmark United Kingdom Prospective Diabetes Study (UKPDS) has conclusively demonstrated the benefits of improved glycemic control in the type 2 patient. For every one milligram percent drop in glycosylated hemoglobin, the risk of microvascular complications (retinopathy, nephropathy and neuropathy) drops 30 to 35%.² The goal should be near normoglycemia in those patients with intellectual, emotional, physical, and financial resources compatible with this goal, and as close to this ideal as possible in other patients. A health care team should be available to provide guidance and support of this goal in appropriate patients.

The risks of hypoglycemia must be balanced against the benefits of improved glycemic control on a case by case basis. Patients should try to achieve the best level of control that they can safely manage without placing themselves at undue risk for hy-

po glycemic complications. This individualization of therapy should occur in consultation with the patient's primary care physician.³

The recently concluded, landmark United Kingdom Prospective Diabetes Study (UKPDS) has conclusively demonstrated the benefits of improved glycemic control in the type 2 patient.



Severe hypoglycemia can result in altered states of consciousness (including seizures and coma), strokes or myocardial infarctions. These can lead to patient injuries and even injuries to others. These complications are less common in type 1 and their risks can be reduced through glycemic monitoring, nutritional education, and appropriate adjustments of hypoglycemic therapy. Patients unable or unwilling to actively participate in glycemic management are not candidates for tight control, nor are patients with significant atherosclerotic disease.

Improvements in glycemic control should be achieved gradually as patients demonstrate their ability to maintain successively more challenging

Abbreviations Used:

PPAR	peroxisome proliferator-activated receptors
UKPDS	United Kingdom Prospective Diabetes Study

glycemic goals. Non-pharmacologic interventions include diet and exercise. Pharmacologic therapies include oral hypoglycemic agents and insulin. Glycemic monitoring is essential in monitoring patients' responses to the treatment regimens. Home glucose monitoring is accomplished via periodic finger sticks. Long term control is evaluated through the measurement of glycosylated hemoglobin levels.⁴

LIFESTYLE MODIFICATION

Medical nutrition therapy is a critical aspect of diabetes management. The goals of nutrition education include glycemic control, weight loss, achievement of serum lipid and blood pressure goals, and the prevention and treatment of hypoglycemia. The overall strategy must include attention to personal lifestyles, and sensitivity to cultural, ethnic, and financial considerations. This level of individualization is highly complex and requires special expertise in implementation. It is recommended that a registered dietitian or specially trained diabetes educator be an active member of the health professional team. Last year legislation was passed in Rhode Island mandating reimbursement for nutrition counseling in patients with diabetes mellitus. This year the federal

government enacted similar legislation.⁵

Regular exercise improves carbohydrate metabolism and insulin receptor sensitivity. Additional benefits can include prevention of macrovascular complications through reduction of cardiovascular disease risk factors; which include hyperlipidemia, hypertension, and obesity. The Surgeon General's Report on Physical Activity and Health recommends a cumulative 30 minutes of moderate physical activity on most days of the week. This is a reasonable goal in patients with type 2 diabetes mellitus. Prior to beginning an exercise program, such patients should undergo a medical evaluation for the presence of micro- and macro-vascular complications that might be worsened by exercise. This evaluation should focus on symptoms, signs, and diagnostic testing for cardiovascular disease, retinopathy, nephropathy, and neuropathy. An individualized exercise program should be designed to minimize the risk of these complications.⁴

PHARMACOTHERAPY

There are currently many choices in hypoglycemic pharmacotherapy for type 2 diabetes. Sulfonylureas were the only option for many years. These agents act by increasing the release of insulin from beta cells. There are now three additional classes of therapy with different and perhaps complementary mechanisms of action: biguanides, alpha-glucosidase inhibitors, and insulin sensitizers.

Metformin is a biguanide, used for many years around the world. It has been available in this country for about three years. This agent interferes with hepatic glucose production by inhibiting both gluconeogenesis and glycogenolysis in the liver. Metformin also increases peripheral glucose utilization. This agent has been associated with improvements in the lipid profile, and is the only current agent associated with modest weight loss. This drug should be avoided in patients at risk for metabolic acidosis; such as those with signs of congestive heart failure, renal or hepatic dysfunction.

Troglitazone is a thiazolidinedione that activates peroxisome proliferator-activated receptors (PPAR) gamma, sensitizing peripheral cells to insulin. This reaction facilitates glucose transport and utilization in muscle and fat cells. It also acts by reducing hepatic glucose production. Recently, troglitazone has been implicated in a few cases of fulminant hepatic failure. The Food and Drug Administration has recommended monitoring of transaminases prior to and during therapy with troglitazone.

Acarbose is an alpha-glucosidase inhibitor that blocks the digestion of carbohydrates in the small bowel. This results in slower absorption of glucose. The most common side effect is gastrointestinal discomfort due to the effect of the relatively undigested complex carbohydrates. Patients may experience bloating and flatulence. These effects can be minimized by increasing the dose slowly.

Insulin remains the only option for Type 2 patients who cannot achieve satisfactory glycemic control on oral hypoglycemic therapy. Insulin must be given sub-cutaneously, either by injection or by implanted pump. Injections may be necessary in single or multiple doses per day. Short-acting, long-acting, and mixed preparations are available. Insulin can be given alone or in combination with oral hypoglycemic agents. The latter is often a useful intermediate step after oral hypoglycemic agent failure.

The figure on "Type 2 Diabetes Treatment Guidelines" is offered for blood glucose management with suggested roles for specific pharmacotherapies. This step approach has become more popular, as different modalities are used at different times to treat this progressive disease.

GLYCEMIC MONITORING

Patients can monitor their blood glucose levels via finger sticks on a frequent basis. In the Diabetes Control and Complications Trial, type 1 patients self-monitored multiple times per day in the intensive treatment group. It is not clear how often patients with type 2 diabetes should self-

monitor. It has been recommended that patients on insulin monitor more frequently than those on oral agents and that those on shorter acting insulins should monitor most frequently (multiple sticks per day). Patients should keep a record of glycemic testing, along with food intake and doses of hypoglycemic drugs.³

Glycosylated hemoglobin testing is the measure of choice for the assessment of long-term glycemic control.³ This is reported as the percentage of hemoglobin that has glucose attached. This measure reflects glycemic control over the preceeding two to three months. This measure should be used to evaluate the response to therapy over this extended period of time, not to make day to day changes in therapeutic regimens. The optimal interval for testing is not known. Currently, it is recommended that patients on insulin should be tested quarterly and that patients controlled by oral agents should be tested as often as necessary to monitor achievement of glycemic goals. Some experts recommend testing twice yearly. Most agree that at least annual testing is prudent. Testing for glycosylated hemoglobin has become a quality indicator in the evaluation of the performance of health plans.⁶

Plasma glucose testing has a lesser role in the evaluation of long-term blood glucose control since glycosylated hemoglobin testing became readily available and has been largely replaced in the evaluation of short-term control by finger-stick self-monitoring. Fasting plasma glucose testing will probably remain the method of choice in screening for diabetes mellitus. The current diagnosis guidelines call for two fasting plasma glucose tests greater than or equal to 126 mg/dL in order to make the diagnosis of diabetes mellitus.³ Other ways to make the diagnosis include two occurrences of the following: symptoms of diabetes mellitus accompanied by a random plasma glucose greater than or equal to 200 mg/dL or a 2 hour plasma glucose greater than or equal to 200 mg/dL on an oral glucose tolerance

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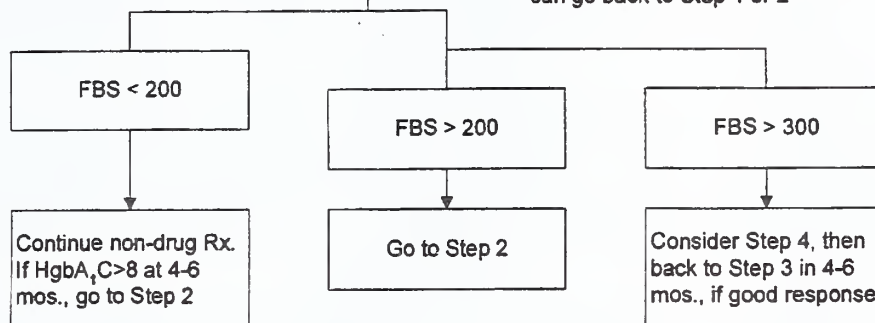
Type 2 Diabetes Treatment Guidelines

Note: If pt thin and has no FH of Type 2 or fails oral agent therapy in <2 years, consider adult autoimmune diabetes (Type 1) - c-peptide testing?

Step 1
Diagnosis
Diet/Exercise

Evaluate response to diet, exercise, education.
Train in home glucose monitoring

Pt's at diagnosis with FBS > 300 often need
Step 5 Insulin Rx for a brief period, then
can go back to Step 1 or 2



Step 2
Monotherapy

Is patient obese, dyslipidemic? (LDL > 160 ↑ Trig.)
creatinine < 1.2, no contraindications

Yes

No, or Metformin
Contraindication

Metformin

Sulfonylurea

Titrate as needed to max dose
(1000 mg bid or 850 tid). If
HgbA1C > 8% at 4-6 mos.

Titrate to near max, *effective*
daily dose—i.e. 10-15 mg
glyburide, 1000 mg
tolbutamide, 20 mg glipizide
If HgbA1C > 8 at 4-6 mos.

Metformin
contraindication

No contraindication

Metformin &
Sulfonylurea

Consider adding
troglitazone or

Metformin &
Sulfonylurea

If fails

? Trial added
acarbose

If fails

Step 3
Combined oral
therapy

Step 4
Hybrid Insulin
Therapy

Metformin or Sulfonylurea & NPH
Insulin at HS. Start at 10 units

Hybrid Therapy Failure (HgbA1C > 8
despite > 40-50 units NPH at HS)

Step 5
Insulin
Monotherapy

NPH Therapy
BID NPH
AM&Supper or HS (start 0.4-0.5 u/kg/day)

Inadequate control, esp. postprandial

Add regular insulin pre-breakfast & supper

test. It is likely that, for reasons of simplification, fasting plasma glucose testing will become the dominant method for diagnosis.

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Screening and Treatment of Diabetic Renal Disease

Jeffrey D. Clement, MD, and Richard A. Cottiero, MD, FACP

Diabetic nephropathy is the leading cause of end-stage renal disease in the United States. Early detection of the diabetic population at the greatest risk for the development of renal failure is of the utmost importance. One of the earliest clinical markers of diabetic nephropathy is a persistent increase in urinary albumin excretion. The normal rate of urinary albumin excretion is less than 20 mg/day; a value between 30 and 300 mg/day is called microalbuminuria and is not detected by the routine urine dipstick. Values above 300 mg/day represent overt proteinuria and are associated with subsequent decline in renal function.

For quantitating microalbuminuria, the 24-hour urine collection for albumin is the most accurate and reproducible test. A simpler screening test is the calculation of the albumin-to-creatinine ratio on a random, untimed urine specimen. A value above 30 mg/g has a high sensitivity for the detection of microalbuminuria. Several disease states can cause reversible (functional) microalbuminuria, at values usually less than 40 mg/day. These include poor glycemic control, urinary tract infection, congestive heart failure, hypertension, and moderate to strenuous exercise. If possible these should be corrected prior to any measurement of urinary albumin excretion rate.

Microalbuminuria is a predictor of progression to renal failure, particularly in patients with poor glucose and poor blood pressure control. Therefore, type 1 and type 2 diabetics should be screened for microalbuminuria on a yearly basis. Screening can be deferred for five years after the onset of disease in type 1 diabetes because microalbuminuria is uncommon before this time; screening should begin at the time of diagnosis of type 2 diabetes, because the disease is frequently unrecognized for several

years prior to diagnosis and end organ damage may have already occurred. Patients should be

screened in the office with a standard urine dipstick; if this is positive, overt diabetic nephropathy should be suspected. Those patients in whom the dipstick is negative should be assayed for microalbuminuria. If persistent microalbuminuria is detected on at least two of three measurements within a six month period, then appropriate treatment can be instituted.

Strict glycemic control with intensive insulin therapy can partially reverse glomerular hypertrophy and hyperfiltration, delay the development of microalbuminuria, and stabilize or decrease protein excretion in patients who already have microalbuminuria.¹ For these reasons, tight glucose control during earlier stages of diabetic nephropathy is advisable. Once overt proteinuria develops, benefits from strict glucose control are less prominent.

Dietary protein restriction has been shown to reduce the rate of decline of glomerular filtration rate (GFR).² However, the benefit to be gained must be weighed against the risk for protein malnutrition, particularly because concurrent fat and carbohydrate restriction in diabetic patients may predispose them to enhanced protein catabolism. Preliminary evidence also suggest a beneficial effect of lipid lowering on albumin excretion.

Therapy which reduces proteinuria is associated with better long term renal outcome. Angiotensin converting enzyme (ACE) inhibitor treatment in microalbuminuric type 1 and type 2 diabetic patients reduces urinary albumin ex-

Abbreviations Used:

ACE	angiotensin converting enzyme
GFR	glomerular filtration rate

cretion and progression to overt diabetic nephropathy, even in normotensive patients.^{3,4} Likewise, a large study of type 1 diabetics with overt proteinuria showed that treatment with an ACE inhibitor reduced proteinuria and the rate of deterioration of renal function, an effect that was seen in both hypertensive and normotensive subjects.⁵ Smaller studies in type 2 diabetics showed a similar effect of ACE inhibition on the rate of loss of creatinine clearance and in proteinuria reduction.^{6,7} Nondihydropyridine calcium channel blockers (diltiazem and verapamil) have also been shown to reduce proteinuria and to lower the rate of loss of creatinine clearance.⁷ Furthermore, the antiproteinuric effects of verapamil and ACE inhibition may be additive; some patients may benefit from combined therapy. Studies of angiotensin receptor antagonists also show reductions in urinary protein excretion. Other classes of antihypertensives, including the dihydropyridine calcium channel blockers, do not reliably reduce proteinuria.

Control of hypertension, regardless of which antihypertensive class is utilized, is most important in delaying progression of diabetic nephropathy. Blood pressure goals should be lower for the diabetic patient than for the nondiabetic patient: systolic blood pressure below 130 mmHg and diastolic blood pressure below 80 mmHg. A combination of an ACE inhibitor and a nondihydropyridine calcium channel blocker may be particularly efficacious. Selective alpha-1 blockers, which can increase insulin sensitivity, should be considered when the blood pressure goal is not fully attained.

Patients should be screened in the office with a standard urine dipstick; if this is positive, overt diabetic nephropathy should be suspected. Those patients in whom the dipstick is negative should be assayed for microalbuminuria.



In summary, all diabetic patients with persistent microalbuminuria or overt proteinuria should be treated with an ACE inhibitor, even if they are normotensive. Lower blood pressure goals for hypertensive diabetic patients are essential. There is insufficient evidence to recommend ACE inhibitor treatment for normotensive, normoalbuminuric diabetic patients, but such patients should try to achieve tight glucose control. An aggressive combined approach may offer optimal protection against disease progression.

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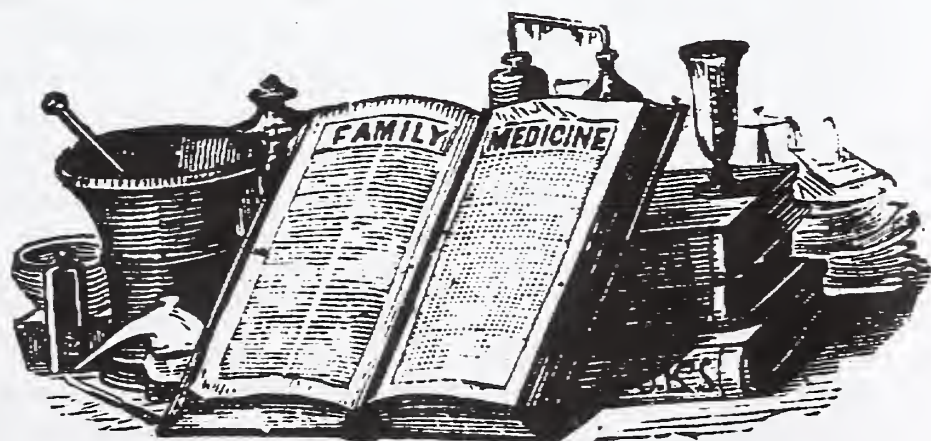
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Coronary Artery Disease and Cerebrovascular Disease Prevention in Diabetes Mellitus: Early Identification and Aggressive Modification of Risk Factors

James V. Hennessey, MD, and Edward Westrick, MD

Diabetes mellitus (DM) is a major risk factor for coronary artery and cerebrovascular diseases. Although not "officially" recognized as a modifiable risk factor for coronary artery and cerebrovascular diseases, the presence of DM should influence preventive efforts through the aggressive treatment of many risk factors. In this column we address the complicated issues of risk stratification and risk factor modification as well as how these concepts can be used to optimize risk reduction for these common, serious diseases in patients with DM. We address the special impact that the presence of DM makes in the treatment of risk factors and how selection of some treatments for hyperglycemia can be influenced by concomitant cardiovascular disease (CVD) risk factors. Lastly, we review important common components to the management of not only DM but also the important modifiable risk factors.

RISK STRATIFICATION AND RISK FACTOR MODIFICATION

Risk factors for CVD include: age, gender, family history, dyslipidemias, hypertension, diabetes mellitus, sedentary lifestyle, cigarette smoking, and obesity. These risk factors can be classified as modifiable or non-modifiable. Modifiable risk factors can be changed and the change is clearly associated with risk reduction. Examples include obesity,¹ dyslipidemias and hypertension. Non-modifiable risk factors either cannot be changed or change has not been associated with risk reduction. Family history is an example of a risk factor that cannot be changed (i.e. patients cannot choose their parents). Diabetes mellitus is a risk factor for which change has not been clearly associated with risk re-

duction of coronary artery or cerebrovascular diseases in prospective randomized controlled clinical trials. However, there is recent evidence that cardiovascular death is correlated with poor glycemic control in a dose-dependent relationship² and results of the recently released landmark United Kingdom Prospective Diabetes Study (UKPDS) indicate a strong beneficial effect of more intensive treatment compared with conventionally treated controls.³ [Note: It is important to think about microvascular complications separately with respect to the role of DM as a risk factor since DM has indeed been demonstrated to be a modifiable risk factor with respect to microvascular complications in type 1 and type 2 DM (i.e. better glycemic control leads to significant improvements in retinopathy and nephropathy).^{3,4}] An optimal prevention strategy uses non-modifiable and modifiable risk factors in risk stratification. Then, based upon the level of risk, treatment goals for modifiable risk factors are developed:

The primary goal of therapy for patients with DM (and without known coronary artery disease) is to reduce LDL cholesterol to less than 130 mg/dL.



Abbreviations Used:

BMI	body mass index
CAD	coronary artery disease
CVD	cardiovascular disease
DM	diabetes mellitus
DQIP	Diabetes Quality Improvement Project
HDL	high density lipoprotein
LDL	low density lipoprotein
TC	total cholesterol
TG	triglycerides
UKPDS	United Kingdom Prospective Diabetes Study

the higher the risk, the more aggressive the goals. The application of this strategy will be illustrated using glycemic control and medication selection, dyslipidemias, hypertension, obesity, and cigarette smoking as modifiable risk factors where prospective data on outcomes exist.

RISK FACTOR IDENTIFICATION

Improvement in glycemic control seems to result in fewer occurrences of myocardial infarction.³ Treatment of the obese type 2 diabetic with metformin has been demonstrated to result in significantly less mortality and specifically, fewer myocardial infarctions than occur in patients given dietary advice alone.⁵

In order to aggressively treat other modifiable risk factors we identify them in the patient with DM. To detect dyslipidemias it is necessary to perform a fasting plasma lipid profile that includes total cholesterol (TC), low density lipoprotein (LDL), high density lipoprotein (HDL), and triglycerides (TG). It has been recommended that all patients with DM have such a test. The optimal interval for re-testing has not been determined, but the American Diabetes Association

Guidelines suggest yearly testing with the option to test less frequently for patients with normal lipidemia.⁶ The Diabetes Quality Improvement Project (DQIP) is considering biennial testing as one in a series of measures of quality of care in its evaluation of the performance of health plans.^{7,8}

Other modifiable risk factors include hypertension, smoking, and obesity. Hypertension is a common co-morbid condition in DM. To diagnose hypertension it is necessary to measure blood pressure according to the recommendations of the Joint National Commission on the Diagnosis, Treatment, and Prevention of Hypertension, 6th Report.⁹ Identification of smoking requires asking patients with DM about their smoking habits. Identification of obesity requires measurement of weight and height and either comparison with normative tables or calculation of Body Mass Index (BMI), which may also be compared to values associated with predicted outcomes. Obesity occupies a unique and pivotal position in the etiology of type 2 DM and its modification is critical in affecting improvements in blood sugar, blood lipids, and blood pressure control, as well as overall CVD risk. Unfortunately the recently published results of the UKPDS outcomes do not allow insight into the effectiveness of weight loss on cardiovascular morbidity and mortality as those assigned to the energy restricted diets lost no weight and actually gained weight during the follow-up period.⁵ All patients with DM should have smoking status assessed. It is typically recommended that blood pressure and weight be measured at each office visit.

DYSLIPIDEMIAS

The primary goal of therapy for patients with DM (and without known coronary artery disease) is to reduce LDL cholesterol to less than 130 mg/dL. A secondary goal is to raise HDL cholesterol. The goal in patients with known coronary artery disease (CAD) is to reduce LDL cholesterol to 100 mg/dL or lower. Recent evidence¹⁰ suggests that DM is equivalent to a history of CAD as a risk factor in pre-

dicting coronary events and an argument has been made to reduce the goal LDL cholesterol in all DM to that of CAD (less than or equal to 100 mg/dL). DQIP will measure the percentage of patients with DM in plans who achieve the first goal of less than 130 mg/dL. Dyslipidemia can influence the selection of hypoglycemic therapy. Weight loss is of course the most effective measure for both diabetes and dyslipidemia. When pharmacologic therapy is deemed necessary, metformin has been demonstrated to have a beneficial effect on lipid profiles and can be recommended as a first line agent in patients with existing dyslipidemias requiring pharmacologic intervention. Conversely, certain lipid lowering agents such as nicotinic acid significantly reduce glucose tolerance and therefore are not considered the best therapeutic choice in the diabetic patient demonstrating dyslipidemia. The ADA recommends as initial therapy, statins with the addition of a resin if necessary to reach the LDL goal.⁶

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HYPERTENSION

Blood pressure reduction in patients with DM has two major benefits: reducing risk for CVD and preventing the progression of nephropathy.⁹ The blood pressure goal in patients with Type 2 DM is < 130/85 mmHg.⁹ In patients with existing nephropathy, ACE inhibitors appear to be the drugs of choice. In patients treated with insulin therapy, beta blockers should be used with caution since these agents can mask adrenergic responses to hypoglycemia, making detection of hy-

poglycemia difficult and blunting counter regulatory response, potentially allowing dangerously low glucose levels to occur. The UKPDS demonstrated however, that despite these recommendations, atenolol and captopril had impressively equivalent impact on cardiovascular complications. The important message from this series of studies is that tight control of blood pressure is associated with reductions in the risk of stroke (44%), congestive heart failure (56%) and overall mortality (32%).¹²

OBESITY

Body mass index (BMI) is becoming the preferred measure of overweight and obesity. This measurement is calculated as the weight in kilograms divided by the height in meters, squared (kg/m²). A patient with a BMI greater than or equal to 30 is considered obese. A patient with a BMI between 25 and 30 is considered overweight.¹³ Treatment of the overweight state is indicated for all diabetic patients and even non-diabetic patients with two or more risk factors for cardiovascular disease or a high waist circumference. Increased risk for cardiovascular mortality is associated with a waist-to-hip ratio >1 or waist >= 40 inches in men, and a waist-to-hip ratio > 0.8 or waist >= 35 inches in women.¹⁴ Treatment of obesity is indicated regardless of risk factor status. The goal of treatment is gradual weight loss, initially 10% of body weight over a 6 month period of time, which may be the only intervention necessary in some patients with DM. Additional weight reduction goals can be set after successful maintenance of previous goal weights. Normalization of body weight, although difficult to achieve without persistent effort, should be the eventual goal of therapy. Obesity can influence the selection of pharmacotherapy for glyce-mic control and some have gone so far as to suggest pharmacotherapy for obesity as a primary drug choice in significantly overweight (>27.5 kg/m²) Type 2 diabetic patients. Since metformin is, in general, associated with some weight loss in short term studies, it may be the preferred agent

in obese or overweight patients with DM unresponsive to diet and exercise alone. The UKPDS experience with overweight subjects indicates that those with metformin gain less weight than those treated with sulfonylureas or insulin but were not different from the conventionally treated subjects who steadily gained weight throughout the study.^{3,5}

SMOKING

Cigarette smoking is an important modifiable risk factor for CVD. Smoking status should be assessed in all patients with DM, and smokers should be advised to quit. Physician advice has meaningful impact on quit rates.¹⁵ Smoking cessation programs are available for patients interested in quitting who need additional support beyond the capacity of the primary care physician.

COMMON INTERVENTIONS

Glycemic control and CVD risk factor management share important common interventions. These include medical nutrition therapy and an exercise program. The proper diet for glycemic control can reduce body weight, improve lipid profiles, and lower blood pressure. A supplemental exercise program can have similar insulin sensitizing effects. These interventions are best used in combination as they help maintain weight loss and enhance energy utilization but should be tailored for individual patient needs after CVD risk assessment.

SUMMARY

Risk factor modification for CVD is an established, effective strategy in patient care. Risk stratification is used to set treatment goals. Lifestyle modification and supplemental pharmacologic therapy are used to accomplish the goals. Patients with DM start with one risk factor, often have additional risk factors, and have higher rates of existing CVD. Vigilance is required in identifying risk factors and persistence in management is often necessary to successfully modify the important risk factors.

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Practical Primary Care Diabetic Foot Screening

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DIABETIC FOOT DISEASE EPIDEMIOLOGY

Fourteen million Americans have diabetes mellitus. Twenty percent of all diabetes-related hospitalizations are for foot complications. Half of all amputations not associated with trauma are performed on patients with diabetes, yet up to half of these may be preventable.^{1,2} Patient and primary care interventions have been shown to reduce the frequency of high risk foot lesions, such as open skin wounds or blisters.³

CHARACTERISTICS OF AN EFFECTIVE PRIMARY CARE FOOT SCREENING TOOL

- 1) It must be easy to perform, and readily incorporated into the usual physical exam.
- 2) It should take a minute or less to complete.
- 3) The screening test should be easily reproducible, and not readily affected by provider technique.
- 4) Interpretation of the results should be straightforward: preferably a simple pass or fail scoring system.
- 5) It should be evidence-based and measure a powerful, independent risk factor for serious diabetic foot disease.

HISTORY AND EXAMINATION

Pertinent foot care history focuses on the peripheral vascular and neuropathic review of systems, inquiring about claudication, glove and stocking numbness, and previous lower extremity ulceration. A brief assessment of patient foot care knowledge is also appropriate.

The traditional exam includes palpation of peripheral pulses, examination of the entire foot and ankle for pressure points and areas of abnormal trauma and callousing (including between the toes for tinea), testing for pitting edema, deep tendon reflexes at the knee and ankle, and possibly testing vibratory sense, light touch and/or pin sensation at the foot. Temperature sensation is less commonly tested in primary care.

Additional screening components of the exam have been either investigated or suggested, including ankle/arm blood pressure index, cutaneous oxygenation testing, and pressure sensation threshold determination using a monofilament nylon filament.

WHICH PARTS OF THE SCREENING EXAM BEST MEET OUR CRITERIA?

The most effective screening for foot vasculopathy found to date is the determination of transcutaneous oxygen tension, which when <30 mmHg has an adjusted odds-ratio for development of diabetic foot ulceration of 58.⁴ This procedure is not readily available in primary care offices, would be hard to perform as part of a general exam, and would require specific training. Since ankle/arm blood pressure index does not seem to predict serious foot pathology, we are left with history of previous ulcer on review of systems as the best predictor of future pathology; not a very sensitive tool!

The situation improves, however, when one looks at neuropathic screening. Both absent ankle reflexes (odds ratio 6.5)

and lack of sensation with the 10g (5.07) Semmes-Weinstein nylon monofilament (odds ratio 18.4) are strong independent risk factors for diabetic foot ulceration.⁴ Both tests meet all of our criteria outlined above for the ideal screening tool; because of stronger experimental evidence, testing with the 10g nylon monofilament is becoming the screening test of choice.^{5,6}

TESTING WITH THE NYLON MONOFILAMENT

The concept behind use of the filament is quite simple: when applied gently to the skin, the filament will buckle at the same pressure every time. This ensures a repeatedly identical stimulus. Four areas on each foot are tested with the patient's eyes closed. The filament is pressed down on the target until it begins to buckle, then removed. The patient says "YES" when the sensation is felt in each location. If the patient does not respond to the stimulus at a given site, it is repeated once. *If any location on either foot is missed twice, the test is abnormal.*

The only precaution is to avoid areas of callous, which will give false negative readings.

USING THE RESULTS

Using the information is quite simple. Patients who feel all eight locations PASS the test, and are screened again at their next yearly exam. Those who miss even one point FAIL, and should be referred to a podiatrist for an evaluation and for ongoing preventive foot care.⁶

(Please refer to the journal attachment for your sample monofilament and instruction card)

THE PODIATRIC EXAMINATION

The podiatric evaluation must be multi-system; all systems play a significant part in determining the patient's future foot care needs. The podiatrist must consider the vascular, dermatological, neurologic osseous structures, as well as muscular function.

A thorough podiatric medical history will include:

1. Determination of the patient's potential risk factors and functional limitations;
2. Review of the patient's physical activities including exercise, work and shoe gear requirements;
3. A thorough past medical history, including medication use, history of allergies and surgeries as well as the family history.

A thorough podiatric physical examination will include:

1. Vascular assessment of gross pulses that include femoral, popliteal, dorsalis pedis as well as posterior tibial pulses. The capillary filling time is also a critical measurement, because the diabetic may have bounding pulses but extremely poor peripheral perfusion.
2. Neurologic examination typically will include evaluation of vibratory sensation, expanded sharp dull, two part discrimination and proprioception in the standard exam.

Expanded focus will frequently evaluate potential areas of nerve impingement including the tarsal tunnel syndrome and lumbar nerve root compression.

3. Dermatologic examination that focuses on hyperkeratotic lesion patterns as well as areas of erythema or skin breakdown. The aim of this examination is to determine if the lesions are due to biomechanical influences, shoe pressure influences or vascular insufficiency. Included in this examination will be debridement of the hyperkeratotic lesions to evaluate the underlying tissue for breakdown and possible presents of skin ulceration.
4. Musculoskeletal evaluation that reviews ranges of motion of the hips, knees, ankle, subtalar, midtarsal and digital joints. Muscle testing will be completed to assess for asymmetry and areas of weakness that may lead to structural breakdown. The biomechanical portion of the musculoskeletal examination will evaluate the forefoot to rearfoot relationship (a relationship that determines excessive or diminished pronation of the foot), the presence or absence of ankle equinus (restriction of ankle dorsiflexion). Gait analysis will be performed to determine the potential for development or worsening of structural deformities.
5. Radiographic evaluation: typically this will be performed if imbalances or deformities are present or if hyperkeratotic lesions overly a bony prominence. These radiographs need to be taken with the patient in a weight-bearing position to determine the true osseous relationships. If ulceration or tissue breakdown is present then a radiograph, a bone scan and/or MRI are indicated.

If the above examination is unremarkable, the treatment is a foot care education program that instructs the patient in proper hygiene and assessment techniques. The patient would also have been instructed on proper shoe gear selection and fit.

If the above examination is unremarkable, but biomechanical imbalances were noted, then specific recommendations would be made for shoes or functional foot orthosis. Occasionally significant chart role deformities such as Hallux Abducto Valgus (Bunion), hammertoes, or other bony prominences would require a recommendation for the patient and primary care physician to consider prophylactic surgical intervention to prevent future ulceration.

Should the podiatrist find evidence of vascular compromise, non-invasive vascular studies should be ordered. If the results were abnormal, the patient should be referred for consultation with a vascular surgeon. Occasionally, values on the ankle brachial index greater than 1 raise concerns about potential calcification of the vascular structures. Calcification prevents full compression during the examination and therefore gives a false impression of adequate perfusion. If the ankle brachial index is greater than 1, a more specific examination such as transcutaneous perfusion oxygen evaluation is appropriate.

If an infection or ulceration is discovered, aggressive care is

required including debridement and full evaluation of the problem. Most importantly we must rule out the depth and extent of ulceration and determine the presence of osteomyelitis. Appropriate treatment must be instituted immediately in conjunction with the primary care physician and possibly the vascular surgeon. Roger Williams Medical Center has developed a critical pathway that has proven extremely successful. This pathway helps to rapidly resolve infection and allow the patient a rapid return to regular activities with minimal tissue loss.

For the neuropathic diabetic patient we recommend a periodic follow-up of 6-8 weeks; for the healthy well-controlled diabetic, a follow-up of 10-12 weeks would be appropriate. A factor to consider for follow-up is the patient's level of compliance with appropriate shoes, exercise and daily foot hygiene. We encourage daily evaluation of the interdigital spaces as well as checking the plantar aspect of both feet for any new or unusual findings.

In summary the podiatric examination is comprehensive. We attempt to allow the patients the ability to ambulate in appropriate shoe gear in order for them to obtain maximum aerobic exercise. Our goal is to rapidly resolve any ulceration and subsequently prevent new ulceration via appropriate shoes, orthosis or surgical intervention.

Patients who feel all eight locations PASS the test, and are screened again at their next yearly exam. Those who miss even one point FAIL, and should be referred to a podiatrist for an evaluation and for ongoing preventive foot care.



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Provider Guidelines for Improving Diabetes Self-Management



Laurie Ruggiero, PhD

GUIDELINES FOR IMPROVING DIABETES SELF-MANAGEMENT

Behavior is integral in preventing and managing chronic disease, especially diabetes. In fact, behavioral contributors may account for greater than 50% of mortality from the leading causes of death.¹

Research suggests that primary care providers feel insufficiently trained in promoting the lifestyle changes needed in diabetes management,² therefore, this article provides information and guidelines to help improve diabetes self-management. Specifically, this article describes the role of behavior in diabetes management and reviews factors that may impact on self-management. In addition, it provides suggestions for the provider to help individuals self-manage diabetes and make the necessary lifestyle changes

Teamwork—the foundation of diabetes care.

The core components of routine diabetes management (Figure 1) involve interaction with health care professionals to obtain or adjust the medication regimen, develop the self-management plan, monitor blood glucose values, evaluate and manage diabetes complications, and obtain ongoing diabetes education. To best accomplish these goals, a collaborative diabetes care team is needed. The team should include the following: the person with diabetes and family members, a physician with expertise in diabetes, a certified diabetes educator, and a registered dietitian. Other professionals, including an exercise physiologist, a mental health professional, a pharmacist, a podiatrist, an ophthalmologist, and a behavioral scientist can complement the team.

The team must work collaboratively to develop the plan. When developing the management plan, the following individual

factors should be considered at a minimum: age, normal daily routine; regular physical activity and eating patterns; marital and family situation; cultural and religious practices; presence of complications or limitations, especially visual, hearing, or physical impairment; and concomitant conditions. The individual with diabetes should remain as actively involved in decision-making as he/she chooses to be. Since s/he will need to implement this plan on a daily basis and make regular decisions about self-management, it is important to empower him/her to take on the leadership role whenever possible and desirable, as well as to assume responsibility for care.³ To develop the best management plan, clinicians need a broad understanding of the person and his/her lifestyle. To underscore this point, this article will refer to these individuals as “*people with diabetes*,” not “*patients*.”

Ongoing Diabetes Education—Providing the basics in information and skills

The initial and *ongoing* diabetes education is critical in managing diabetes over the long-term. Research has shown that diabetes education should include both information and behavioral skills training (e.g., insulin administration) to be most effective.⁴ The timing, format, and content of education should be tailored to the individual's preferred learning style (e.g., reading, watching videos) visual acuity, hearing, literacy level, educational level, attention or cognitive challenges, and motivation to learn. In addition, it is important to re-assess a person's diabetes-related knowledge and skills periodically and to provide education and/or referral to a diabetes educator where needed.

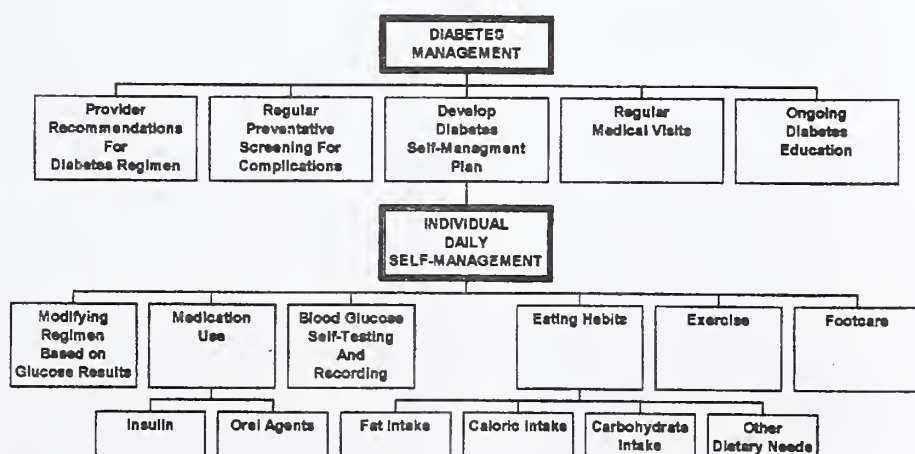
Self-Management—The cornerstone of effective diabetes management.

The cumulative number of hours spent on diabetes management activities (the first level of Figure 1) generally total well under 24 hours per year - or less than 1% of the total number of hours spent managing diabetes for an individual each year. In contrast, individuals with diabetes generally need to take medication several times per day, self-test blood glucose levels regularly and record the results, closely follow a healthy eating plan, exercise regularly, and perform footcare, among other daily tasks. Individuals with other cardiovascular disease behavioral risk factors, such as obesity or smoking, will need to make additional lifestyle modifications. In general, greater than 99% of the time spent managing diabetes is spent in self-management ac-

Abbreviations Used:

ADA	American Diabetes Association
DCCT	Diabetes Complications and Control Trial

DIABETES SELF-MANAGEMENT IS THE CORNERSTONE OF EFFECTIVE DIABETES MANAGEMENT



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tivities. Therefore, self-management is often considered the *cornerstone* of diabetes management.

Once the diagnosis is made, the initial management plan is established, and key education has been provided, attention should focus on helping the person self-manage diabetes as well as possible. Self-management involves establishing, modifying, or maintaining key health behaviors. In helping people develop the best self-management patterns, it is necessary to understand the complexity of factors that may have an impact on self-care. It is important to assess the role that these factors play in self-management and be sure that appropriate interventions are provided.

FACTORS IMPACTING SELF-MANAGEMENT

Individual Contextual Factors.

A number of contextual factors that pre-date the diagnosis of diabetes may play a role in a person's self-management patterns. These include culture and language, general health beliefs, level of education, financial situation, etc. The background of a person can offer support for managing diabetes or could pose special challenges. For example, a person who believes that health is solely a matter of fate may be less likely to follow a self-care plan.

To understand a person's self-management patterns and assist him/her in managing diabetes, it is important to be aware of important contextual factors. The American Diabetes Association (ADA)⁵ recommends that such factors be assessed as part of the medical history at the initial visit. Furthermore, it is helpful to identify any contextual challenges and where appropriate overcome barriers or further individualize the self-care recommendations. Other diabetes care team members, such as the educator or mental health professional, can help with these tasks.

Psychosocial Factors.

Psychosocial factors can also contribute to diabetes self-management.⁶ Certain factors, like social support, may promote effective self-care while others, like depression or stress, may interfere with self-care. Important psychosocial factors include marital and family relationships, general psychological adjustment, diabetes-related adjustment, stress, social support, coping style, and cognitive maturity. Diabetes may also pose new anxieties such as fear of hypoglycemia and may escalate others such as fear of weight gain. In addition, individuals' personal beliefs⁷ about diabetes,

(e.g., perceived severity of diabetes) may influence self-care behavior. When working with people with diabetes, it is important to assess these factors. In fact, the ADA⁵ recommends that psychosocial adjustment and adherence to self-management tasks be evaluated at *each* medical visit. The mental health professional on the team can work with individuals regarding psychosocial factors that impact on self-care.

Disease State And Treatment Specific Factors.

Research on "compliance" has indicated that the more complex the regimen, the less likely that a person will follow it over the long term. Diabetes self-management is one of the most complex medical regimens for disease management. Furthermore, in general, diabetes self-management is a lifelong responsibility. Therefore, care should be taken to make the regimen as simple as possible. For example, if it is possible to recommend a single daily dose medication that has the same effect as a multiple dose, the single dose should be the choice. Also, people quickly forget much of what they are told, especially when they are given a long list of recommendations at one time or when they are in an anxiety-producing situation, such as may occur when talking with their doctor. So when making recommendations, be clear and specific, make sure the person understands them, and write them down to improve accurate recall. When teaching the person a new skill, such as injecting insulin, first demonstrate the correct approach, then observe to be sure that the person can perform the task.

Other treatment-related factors, such as aversiveness of self-care tasks (e.g., injecting insulin), consistency in the recommendations made by different providers, quality of interactions and relationships with providers (e.g., perceived as warm and caring), and factors related to healthcare delivery (e.g., delay in getting appointment) may also have an impact on self-management. It is important to be aware of these potential barriers to self-care.

Disease and physiological factors can also complicate self-care and may require increased attention or modifications in the self-management plan. For example, transitions such as adolescence and menopause, illness, and emotional stress can all impact on glucose control and may disrupt effective self-management. Therefore, it is important that the physician periodically re-assess the self-management plan and a person's adherence with the plan, making changes when and where necessary. It may

also be beneficial to refer the person to a diabetes educator or mental health professional for additional support.

HELPING PEOPLE CHANGE SELF-MANAGEMENT BEHAVIOR

In addition to identifying the factors that may have an impact on self-care, providers should employ theory- and evidence-based behavior change approaches to promote the behavior change needed to effectively manage diabetes. Research on one promising theory that has application in diabetes management⁸, the Transtheoretical Model, has indicated that people pass through different stages of motivational readiness when making a change. These include five stages of change—precontemplation, contemplation, preparation, action, and maintenance. In the precontemplation stage, the person is not intending to make a change in the foreseeable future. In the contemplation stage, a person is intending to make a change in the foreseeable future but not the immediate future. A person in the preparation stage is intending to take action in the immediate future. A person in the action stage has recently reached a behavioral goal while a person in the maintenance stage has continued a new behavior for at least six months.

The model suggests that movement through the stages is cyclical. That is, people may move forward and then recycle back to an earlier stage several times before changing for good. Therefore, it is important to view recycling as a valuable learning experience and not a failure. This experience may provide the information needed to help the person reach the goal on the next attempt. Also, when using this model, it is important to redefine success. Any forward movement, not just movement to the action stage, should be seen as a "success." For example, if a person has been in the precontemplation stage for years on smoking cessation, and has recently moved forward to the contemplation stage, this is an important success.

Research has indicated that providing individualized intervention approaches matched to the person's stage of change is helpful in changing health behavior.⁹ A number of key variables are important in matching the intervention approach to the person's level of motivational readiness, including perceived pros and cons of making the change (i.e., decisional balance), perceived situational self-efficacy and temptations, and processes of change. Based on this model, different variables and processes of change are emphasized in dif-

ferent stages to help the person successfully move through the stages to long-term maintenance of a healthy habit.

Knowledge of a person's stage will help the provider tailor the advice and assistance. In particular, a key focus in the early stages is motivating the person to consider change, while a key focus in the later stages is helping the person make the desired change. For example, the focus for the contemplation stage is to help the person get ready for change while the focus for the preparation stage is to help the person make the desired change (i.e., take action) in the immediate future. Some tips for the provider to use to help the person in contemplation get ready for behavior change include: informing the person of all of the benefits of the desired change; helping the person identify and overcome any barriers to change; encouraging the person to experiment with small steps toward the final goal, and building the person's confidence in his or her ability to change. Some tips to help a person in the preparation stage make the change in the immediate future include: help the person develop a clear and realistic plan; make a firm commitment to change; plan ahead for temptations to return to the old behavior, and get support for making the desired change. In addition, rewards for positive changes have long been recognized as a powerful incentive.¹⁰ Rewards can come in many forms and need not cost money. For example, a compliment from a provider about sticking with an exercise program can be a powerful reward. It is important to help people identify self-rewards, such as giving themselves "a mental pat-on-the-back," buying a novel, or playing golf. (Read *Changing For Good*¹¹ for more information on this model; read Ruggiero & Prochaska⁸ for information on its application in diabetes.).

SUMMARY OF PROVIDER GUIDELINES FOR PROMOTING OPTIMAL SELF-MANAGEMENT

Guideline #1: Form a collaborative diabetes care team, establish shared management goals, and be sure that all medical team members provide messages that are consistent with these goals.

Guideline # 2: Develop the diabetes care plan in concert with the person. Take individual characteristics and lifestyle factors into account in tailoring the plan. Empower the individual to take on the preferred leadership role and level of responsibility for managing diabetes.

Guideline #3: Provide diabetes knowledge and skills training on an ongoing basis.

Research on one promising theory that has application in diabetes management, the Transtheoretical Model, has indicated that people pass through different stages of motivational readiness when making a change.



Check to be sure the person understands any new information or self-care task you teach.

Guideline #4: Provide clear and specific recommendations and provide assistance where needed for *all* diabetes self-care and cardiovascular disease risk factor reduction behaviors. Neglecting to address an unhealthy behavior, such as smoking, can send a message that this behavior is not important to change.

Guideline # 5: At each visit, assess how closely the individual is following *each* self-management task. Also follow-up on each recommended lifestyle change, such as quitting smoking.

Guideline # 6: Regularly assess psychosocial functioning, especially emotional, marital, occupational, and family functioning, and its impact on diabetes self-care. Provide interventions or make referrals where needed to help facilitate effective diabetes management.

Guideline #7: Remember self-management of diabetes is a *challenging lifelong and full-time* task. Make the self-care plan as simple and realistic as possible. Check the person's understanding of your instructions and write them down.

Guideline # 8: Periodically re-assess the self-management plan, especially during major life changes; and modify the plan where needed.

Guideline #9: Assess a person's stage of motivational readiness for change for *each* self-care behavior. Match the information provided and intervention approach to the stage of change.

Guideline #10: Provide praise for steps taken toward the final self-management goal—remember use of rewards, especially compliments from providers, can be a powerful motivator of change.

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Diabetes Legislation, Programs and Projects

Dona Goldman, RN, MPH, Joann Lindenmayer, DVM, MPH, and Edward Westrick, MD, MS

LEGISLATION

NEW DIABETES LEGISLATION: Rhode Island

Rhode Island law, enacted January 1997, requires that every individual or group health insurance contract, plan or policy provide reimbursement for the following diabetes-related supplies and services if prescribed by a physician: blood glucose monitors, blood glucose monitors for the legally blind, and test strips for glucose monitors or for visual reading, insulin, injection aids, cartridges for the legally blind, syringes, insulin pumps and appurtenances, insulin infusion devices, oral agents for controlling blood sugar, therapeutic/molded shoes for prevention of amputations and any new equipment and supplies prescribed by a physician and approved by the federal Food and Drug Administration (FDA).

Diabetes self-management education by certified diabetes educators, including nurses, dietitians and pharmacists, is also covered. Education includes one-to-one counseling, group sessions, and home visits. A physician's referral is necessary for reimbursement. Insurers in Rhode Island have designated the Department of Health's Diabetes Education Certification Program as the credentialing body for education. For information, call the Department's Diabetes Control Program at 222-3442.

The 1998-99 "Third Party Directory for Diabetes Supplies and Services" describes the new legislation and each insurer's diabetes-related coverage. It is available at no cost. A sample copy will be sent to each physician in the State.

NEW DIABETES LEGISLATION: National

Under new legislation (July 1, 1998), Medicare (Part B and Medicare Managed Care) will reimburse all patients with diabetes regardless of treatment methods for blood glucose monitors and blood glucose monitoring strips. A physician must document that the patient or care giver is capable of being trained to use the monitor and has completed training. Medicare will pay for up to 100 test strips and 100 lancets every month for persons who are insulin-treated. If a person is non-insulin treated, Medicare will pay for up to 50 strips and 50 lancets every 2 months. (In both instances, Medicare may reimburse for additional supplies, if physicians document the need.)

Medicare will also pay for diabetes education services. Previously, only hospital-based programs were eligible for reimbursement; now any program recognized by the ADA, and ordered by a physician as a necessary part of treatment, is eligible.

Abbreviations Used:

ADA	American Diabetes Association
BMI	body mass index
BRFSS	Behavioral Risk Factor Surveillance System
CDC	Centers for Disease Control and Prevention
DEARS	Diabetes Education Assessment Referral and Screening
DF-RI	Diabetes Foundation of Rhode Island
DQIP	Diabetes Quality Improvement Project
FDA	Food and Drug Administration
FPG	fasting plasma glucose
GDM	gestational diabetes mellitus
HDL	High density lipoprotein
NCQA	National Committee for Quality Assurance
NDEP	National Diabetes Education Program
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
RIDCP	Rhode Island Diabetes Control Program
RIDOH	Rhode Island Department of Health
SWDSP	Statewide Diabetes Screening Project

PROGRAMS

RI DIABETES CONTROL PROGRAM

On July 1, 1998, the Rhode Island Diabetes Control Program was awarded funding from the Centers for Disease Control and Prevention (CDC) to expand its activities from a capacity-building ("Core") Program to a statewide Diabetes Comprehensive Program. Rhode Island is one of the first nine states and territories to receive this expanded funding. Since 1979 the RIDCP has provided programs in health systems and organizations to increase the quality of care for persons with diabetes, to address diabetes and other chronic disease risk prevention in a comprehensive manner, to provide public, patient and professional education, and to address issues related to care for disadvantaged populations. Among the features of the Diabetes Comprehensive Program are the following:

Diabetes Strategic Plan

The Diabetes Comprehensive Program will finalize a strategic plan that addresses the needs and barriers to care. The Diabetes Advisory Council, which provides leadership and oversight to the RIDCP activities, is responsible for overseeing development of the plan and for ensuring it meets national and State Healthy People Objectives for the Year 2010.

continued on Page 363



LEAP PROGRAM

(LOWER EXTREMITY AMPUTATION PREVENTION)

GILLIS W. LONG HANSEN'S DISEASE CENTER

5445 POINT CLAIR ROAD, CARVILLE, LA 71721

(504) 642-4714, (504) 642-4774 FAX

The LEAP FILAMENT was developed at Carville by the LEAP staff in 1996. It was originally designed to be used in a Patient Empowerment Program study to determine if a patient could use a simple filament; test themselves (or have a family member assist them); and get the right answer without specific training. The study was successfully completed and the results appeared in the January 1998 issue of *Diabetes Care*.

Following the study, we began to use the LEAP FILAMENT as a teaching filament for use by seminar participants. We recently made several design revisions and are pleased to provide you, free of charge, with:

A LEAP FILAMENT (with assembly instructions);
and a Patient Empowerment Program Foot Screen.

How to Assemble the LEAP Filament

1. With the adhesive side up, remove the liner. Hold the orange nylon about halfway down its length. Place the tip of the nylon **PRECISELY** on the small dot and proceed, adhering the filament down the dotted line.

We cannot stress enough the need for the tip of the filament to be placed on the dot. By starting on the dot, the visible filament, when the process is completed, will be 38 mm in length. That is the length required to deliver 10 grams of force.

2. After applying the orange nylon, fold at the crease and press tightly.
3. Insert the card into the envelope and then insert the filament by holding the orange nylon and inserting the handle first so that it rests flat on the bottom of the envelope.
Make sure the filament is inserted straight into the envelope. If the nylon touches the side of the envelope, it will eventually develop a curve which, if significant, could distort the accuracy of the results.

Foot Screen Instructions

(You may screen your own feet, or ask a relative, friend or neighbor to do it for you.)

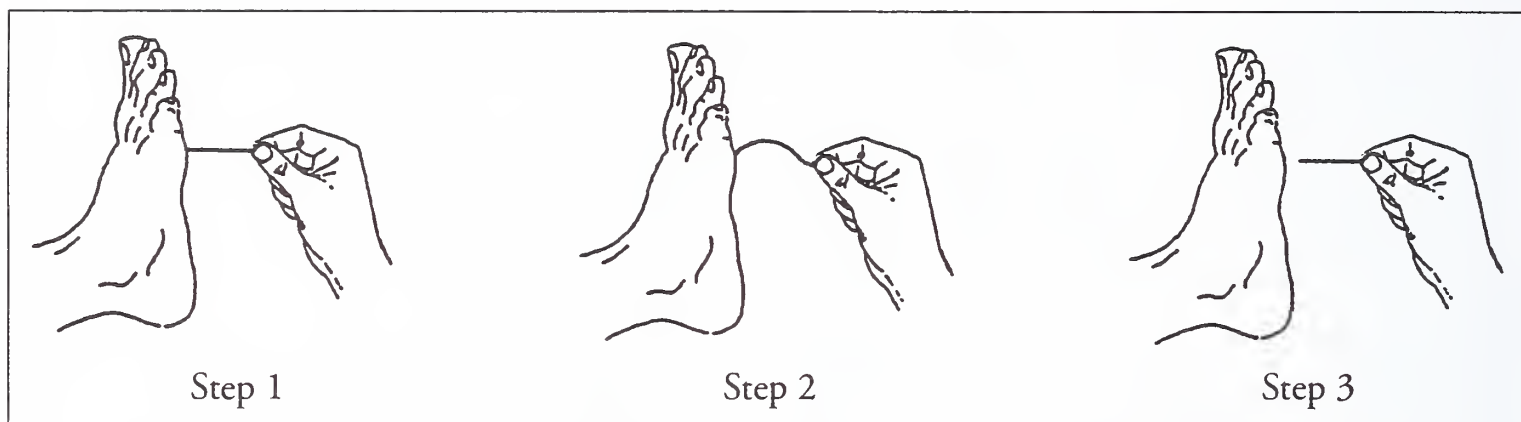
1. Holding the filament by the paper handle, touch each foot at the four circled sites as show in Figure 1 (next page). **Note:** *Touch the filament along side of and NOT on a scar, callous or ulcer.*
2. Touch the filament to the skin with a smooth motion, lasting a second or two, as in the Step 1, Step 2, and Step 3 drawings on the next page.
3. Push hard enough with the filament to make it bend (See Step 2).
4. Place a ⊕ in the circle if you can feel the filament at that site and a ⊖ if you cannot feel a filament at that site.

NOTICE: If you have a ⊖ in any circle, take this form as soon as possible to your nurse or physician.

Diabetic Foot Screen: Patient Empowerment Program LEAP Program, Gillis W. Long Hansen's Disease Center, 5445 Point Clair Road, Carville, LA 70721		Date: _____
Patient's Name (Last, First, Middle) _____		ID No.: _____



Figure 1



Provider: If you have a question about sensory testing, please call (800) 642-2477

For more information, see Quevedo and Werber, "Practical Primary Care Foot Screening," this issue.

CME Background Information

This CME activity is sponsored by Brown University School of Medicine

TARGET AUDIENCE

This enduring material is designed for primary care physicians.

CME OBJECTIVES

After completing this CME activity, the primary care physician will be able to:

- Explain strategies for the prevention of microvascular and macrovascular complications of type 2 diabetes mellitus: retinopathy, nephropathy, neuropathy, peripheral arterial disease, coronary heart disease and cerebrovascular disease.
- Recognize new legislation, programs and projects at the national and state levels related to diabetes care: Statewide Diabetes Screening Program, CDC/DCP Comprehensive Grant, Diabetes Legislation in Rhode Island, Rhode Island Quality Partners projects, National Diabetes Education Program, Diabetes Quality Improvement Project, Provider Recognition Award and new HCFA reimbursement.
- Develop a system for diabetes care using existing multidisciplinary resources in the health care community: current barriers, team approach, community resources and specialty referral guidelines.
- Identify barriers to diabetes self-management: diet, exercise, smoking, self-monitoring and medication compliance.

NEEDS ASSESSMENT

The need for this educational activity was expressed by the Diabetes/Hypertension Conference Planning Committee while selecting topics for an American Heart Association sponsored Conference. Conference topics were expanded and written for publication.

ACCREDITATION STATEMENT

Brown University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education.

CREDIT DESIGNATION

Brown University School of Medicine designates this education activity for 2 hours in category 1 credit toward the AMA Physician's Recognition Award. Credit can be obtained by reading the issue and completing the quiz on this page. The estimated time for completion of this activity is 2 hours.

DATE OF ORIGINAL RELEASE

This issue was published in November 1998. This activity is eligible for CME credit through August 31, 1999.

AUTHOR LIST

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AUTHOR DISCLOSURE

In the spirit of full disclosure and in compliance with all Accreditation Council for Continuing Medical Education Essentials, Standards, and guidelines, all authors for this CME activity were asked to complete full disclosure statements. The information received is as follows:

Dr. Cottiero has received grant and research support from Novartis Corporation.

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Dr. Westrick is a consultant for MIM ProMark a pharmacy benefits management company.

Dr. Ruggiero has received grant and research support from Lifespan and also is a member of their speaker's bureau.

DISCUSSION OF INVESTIGATIONAL INFORMATION

The authors have stated there is no off-label or investigational use.

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CME QUESTIONS: TRUE OR FALSE

1. Annual funduscopic examination by primary care physicians is the best strategy for detecting early diabetic retinopathy.
2. Diabetic patients who are screened negative by standard urine dipstick should be assayed for microalbuminuria.
3. The Diabetes Quality Improvement Project is a joint effort by the Centers for Disease Control and the National Institutes of Health designed to educate the public about diabetes.
4. According to the Transtheoretical Model, patients in the stage of Precontemplation are ready to make behavior change in the immediate future.
5. Self-management of diabetes is a complex, lifelong challenge, that often requires the assistance of a collaborative multidisciplinary care team.
6. The goals of podiatric care in diabetes are to prevent tissue loss and allow an active lifestyle.
7. There are no effective screening tools for early diabetic foot disease.
8. Diabetic patients with arthritis or significant weight problems are not candidates for exercise.
9. Elderly diabetic patients with risk factors for cardiovascular disease should undergo exercise tolerance testing prior to engaging in a vigorous exercise program.
10. The Statewide Diabetes Screening Project will try to reach people 35 years or older who have not been diagnosed with diabetes.
11. Coverage for diabetes education and supplies is now mandated by both RI state and federal law.
12. Tight control of blood sugar reduces the risk for microvascular complications in type 1 but not type 2 diabetes.
13. Cardiovascular disease can be prevented by controlling blood pressure and cholesterol in patients with type 2 diabetes.
14. Patients with diabetes should have their eyes and urine checked at least every three months.
15. The United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that tight blood sugar control is beneficial in type 2 diabetes; the Diabetes Complications and Control Trial (DCCT) demonstrated the beneficial effect in type 1 diabetes.

CME REGISTRATION FORM

1.	T	F	Print or type
2.	T	F	Name _____ Degree _____
3.	T	F	Address _____
4.	T	F	_____
5.	T	F	City, State, Zip _____
6.	T	F	Phone () _____
7.	T	F	Fax () _____
8.	T	F	<input type="checkbox"/> Hospital <input type="checkbox"/> Private Practice <input type="checkbox"/> Resident <input type="checkbox"/> Intern <input type="checkbox"/> Other _____

DEADLINE FOR SUBMISSION

For credit to be received, please fax or mail your registration and submit your answers no later than August 31, 1999. Mail the registration form to: Office of Continuing Medical Education, Brown University School of Medicine, Box G-A2, Providence, RI 02912 or fax to (401) 863-2660.

KEEPING A COPY FOR YOUR FILES

Retain a copy of your answers and compare them with the correct answers, which we will make available upon request, and receipt of submission requirements.

15. T F

EVALUATION

Please evaluate the effectiveness of the CME activity on a scale of 1 to 5 (1 being poor; 5 being excellent) by circling your choice.

	Poor			Excellent
	1	2	3	4 5
1. Overall quality of this CME activity	1	2	3	4 5
2. Content	1	2	3	4 5
3. Format	1	2	3	4 5
4. Faculty	1	2	3	4 5
5. Achievement of educational objectives:				
A. Explain strategies for prevention of microvascular and macrovascular complications of type 2 diabetes mellitus.	1	2	3	4 5
B. Recognize new legislation, programs and projects at the national and state levels related to diabetes care.	1	2	3	4 5
C. Develop a system for diabetes care using existing multidisciplinary resources in the health care community.	1	2	3	4 5
D. Identify barriers to diabetes self-management.	1	2	3	4 5
6. This CME activity provided a balanced, scientifically rigorous presentation of therapeutic options related to the topic, without commercial bias.	1	2	3	4 5
7. Please comment on the impact that this CME activity might have on your management of patients.	_____			

8. Additional comments and/or suggested topics for future CME activities.	_____			

Diabetes Self-Management Education

The RIDCP Certified Diabetes Outpatient Educator and Education Site Program currently has 120 diabetes educators (nurses, dietitians, pharmacists) and 26 certified sites statewide. Approximately 5,000 persons receive diabetes education on an annual basis. Certified programs take place in hospitals, physician office practices, renal dialysis centers, visiting nurse associations, work sites, the Indian Health Center, managed care organizations, the Veterans Administration Hospital, the Naval Hospital, neighborhood health centers, and primary care centers. Programs are available free of charge for those unable to pay; various sites offer multi-cultural and multi-lingual education. The program certifies 50 additional educators annually. Brochures are available for physicians and their patients at no cost from the Rhode Island Diabetes Control Program.

Diabetes and Chronic Disease Risk Factor Project

This project addresses the disproportionate burden of diabetes among high risk disadvantaged and minority populations by implementing an integrated, comprehensive approach. Components include implementing and institutionalizing diabetes standards of care as well as risk reduction activities related to diabetes, cardiovascular disease and cancer. A computerized system has been developed to monitor patients' receipt of clinical preventive services, to cue physicians about needed services and to provide feedback to physicians for continuous quality improvement. The project is ongoing at three sites: a community health center, a hospital-based primary care clinic, and a managed care organization. Preliminary data analysis of 500 patient records as well as interviews with site staff demonstrate that the intervention has increased knowledge and awareness of standards among providers and has increased adherence to diabetes standards of care. The new Diabetes Comprehensive Program will extend this intervention to additional neighborhood health centers, hospital-based primary care clinics, and the Indian health center.

Comprehensive Multi-disciplinary Approach to Diabetes Care for Persons >65 years of age.

The RIDCP, in collaboration with Harvard Pilgrim Health Care of New England and Rhode Island Quality Partners, will institute a model "Diabetes Morning" to provide assessment of diabetes management and education to persons 65 years of age and older, who comprise 50% of persons with diabetes in the State. This program, based on a program developed by Kaiser Permanente and adapted by Harvard Pilgrim Health Care, uses a systems-based intervention with a group visit. The program seeks to 1) improve efficient delivery of care, 2) increase knowledge of standards of care, 3) increase patient motivation to improve self-management behavior, 4) expose patients to a multi-disciplinary team, 5) provide the physician and patient easy access to a total team approach. Fifteen to twenty persons with diabetes are invited to a half day group session. A multi-disciplinary team including a physician conducts

laboratory tests, assessments of feet, diet, medication compliance, and blood sugar monitoring skills, provides referrals for dilated eye exams and administers pneumonia and influenza immunizations when needed. The education component includes short presentations by a physician, nurse, dietitian and pharmacist. Physicians hold brief individual appointments with patients to review results of laboratory tests, to answer questions and to encourage patients to improve diabetes self-management. Harvard Pilgrim Health Plan of New England has found high satisfaction for both patients and providers. Dr. Stephen Quevedo reported, "I knew this would be good, but I did not know this would be so much fun. This is what we should really do more often." Reimbursement codes for the components of this program, both for the group education and the one to one counseling, exist.

Statewide Diabetes Screening Project (SWDSP)

The Statewide Diabetes Screening Project (SWDSP) is a collaborative effort of the RIDCP and the Diabetes Foundation of Rhode Island (DF-RI). Participants include all major health plans in Rhode Island, CVS pharmacy, experts in diabetes care, the business community, voluntary organizations, health care professionals, consumers, and community agencies.

The project offers a unique public health approach to diabetes screening that builds on guidelines issued jointly by the CDC and the American Diabetes Association (ADA). These guidelines, published as clinical practice recommendations in *Diabetes Care*, January 1998, state that "screening of high risk individuals should be considered at 3 year intervals," and lists the following major risk factors for diabetes mellitus:

- * Family history of diabetes (at least one parent or sibling with diabetes);
- * Obesity (20% over desired body weight or body mass index [BMI] ≥ 27 kg/m²);
- * Race/ethnicity (Black/African-Americans, Hispanic-Americans, Native Americans, Asian-Americans, Pacific Islanders);
- * Age ≥ 45 years;
- * Previously identified impaired fasting glucose (IFG) or impaired glucose tolerance (IGT);
- * Hypertension ($\geq 140/90$ mm Hg);
- * High density lipoprotein (HDL) cholesterol level ≥ 35 mg/dl (0.90 mol/l) and/or a triglyceride level ≥ 250 mg/dl (2.82 mol/l);
- * History of gestational diabetes mellitus (GDM) or delivery of a baby that weighed more than 9 pounds at birth.

Furthermore, the CDC and ADA recently established new criteria for the diagnosis of diabetes, which can now be made on the basis of two FPG tests with blood glucose ≥ 126 mg/dl, performed on separate days.

Briefly, the SWDSP will randomize Rhode Island households to receive one of three screening interventions in the mail—two urine test strips, two risk questionnaires developed by the ADA and refined by the CDC, or two invitations for FPG tests. People 45 years of age and over who have not been diagnosed with diabetes will be eligible to participate. The mailing will be accompanied by a statewide media campaign and by comprehensive professional education efforts targeted at physicians, nurses, pharmacists, dietitians, podiatrists, optometrists, and medical office staff. Persons whose screening tests are positive, or who accept an invitation for a FPG test, will be offered the test. People whose blood glucose is 126 mg/dl by FPG will be strongly encouraged and assisted to seek confirmatory testing from their personal physicians. Persons without access to medical care will be provided access to primary care through the Diabetes Resource Centers (see Resources).

One objective of the SWDSP is to determine whether recipients will take a screening test in the privacy of their homes (or will accept an invitation for a FPG). If they do, a second objective is to determine whether receiving a positive screening test result or accepting an invitation for a FPG will cause people to act on that information, that is, seek a FPG test offered through the RIDOH or contact their physician for the same.

Two features of the public health climate in Rhode Island make this project feasible—the existence of two Diabetes Resource Centers and plans for the development of three new centers that serve people with diabetes who have no health insurance, and the passage of legislation that requires third party insurers to cover diabetes supplies and medications. Together with the strong diabetes network established in this state over the past twenty years, these provide a safety net for individuals who are subsequently diagnosed as having diabetes, regardless of whether or not they participate in the health care system. Because these safeguards exist, it may be possible to begin to identify the approximately 15,000 Rhode Islanders who are estimated to have diabetes (primarily type 2) but who are unaware of it.

The project will be implemented on Aquidneck Island in 1999.

The Statewide Diabetes Screening Project has received political support from Governor Almond, the Rhode Island congressional delegation, Rhode Island legislators, and the Attorney General. The Advisory Committee to the Project, chaired by Dr. Patricia A. Nolan, Director of the RIDOH, includes representatives of all major health plans in Rhode Island, as well as members of the business, private voluntary organization, health care professional, and consumer communities.

Major accomplishments to date include establishment of a statewide Advisory Committee and eight task groups (technical, medical management, legal-ethical, professional education, public education, public relations, fund raising, and community outreach), development of a comprehensive time line and project procedures, inclusion of 12 ques-

tions on the State's Behavioral Risk Factor Surveillance System (BRFSS) to establish a baseline for the media campaign, and focus-testing of the screening tests.

AMERICAN DIABETES ASSOCIATION PROVIDER RECOGNITION PROGRAM

The American Diabetes Association's (ADA) Provider Recognition Program^{1,2} is a voluntary opportunity for individual physicians or physician groups to be recognized for providing high quality diabetes care. Co-sponsored by the National Committee for Quality Assurance (NCQA), the program assesses performance on 11 measures of care for adult and 8 measures of care for pediatric patients. The program was developed to improve diabetes care "by 1) focusing the health care community, purchasers of health care, consumers, and other interested organizations on the 11 key measures of diabetes care, and 2) identifying, motivating, and commending physicians who are providing quality diabetes care."

Recognized physicians appear in ADA and NCQA print media and on those organizations' web sites. The lists are shared with health plans, employer groups, and insurers. Physicians who apply for but do not achieve recognition status will not be identified. All information provided by applicants is confidential. Recognized physicians may advertise their status within guidelines established by the ADA and NCQA.

Application for recognition includes an application form, abstraction of data elements from medical records, and the administration of a patient survey. The sample size for individual physicians consists of 35 patients. There is a \$65 fee for application materials and a \$300 fee that accompanies data submission.

The two levels of achievement are: "Recognition," and "Recognition with Distinction." Recognition with Distinction denotes physicians who demonstrate performance that greatly exceeds the acceptable criteria on the 11 measures. Recognition is valid for three years. As of August 1998 there were over 80 physicians/physician groups recognized nationally, one in RI.

NATIONAL DIABETES EDUCATION PROGRAM

The National Diabetes Education Program⁵ (NDEP) is a joint effort of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) and the Division of Diabetes Translation of the Centers for Disease Control and Prevention (CDC). "The goal of the NDEP is to reduce the suffering and death resulting from diabetes and its complications, through programs which increase public and professional awareness of the seriousness of diabetes and the value of its treatment." This national campaign will begin soon.

There are seven guiding principles listed and justified below.

Principle 1: Screening High Risk People and Diagnosing Diabetes

One third of people with diabetes remain undiagnosed. Finding and treating diabetes early can improve health outcomes for people with diabetes. Therefore, routine screening and correct diagnosis are essential.

Principle 2: On-Going Care

People with diabetes should always receive high-quality care on an ongoing basis to ensure that they are taking good care of their diabetes, and to make changes to their treatment plan when needed to achieve control of the disease.

Principle 3: Diabetes Education

People with diabetes and their family members have the right to accurate information and education needed for diabetes self-care.

Principle 4: Treating Hyperglycemia

Blood glucose levels should be kept as near to normal levels as is safely possible. The target range should be based on an overall assessment of the person's health.

Principle 5: Self-Monitoring of Blood Glucose Control and Hemoglobin A1c (HbA1c)

Blood glucose levels and hemoglobin A1c values should be measured on a routine basis using current, reliable methods.

Principle 6: Preventing and Diagnosing Long-term Diabetes Problems

Excellent diabetes care can greatly lower the chances of developing long-term diabetes problems.

Principle 7: Screening For and Treating Long-term Diabetes Problems

People with diabetes should have regular exams to help find and treat long-term diabetes problems. All long-term diabetes problems have effective treatments.

PROJECTS

DIABETES QUALITY IMPROVEMENT PROJECT

(Initial Measure Set From The Diabetes Quality Improvement Project, March 13, 1998). Diabetes Mellitus has become a tracer condition for the measurement of health care quality. The Diabetes Quality Improvement Project (DQIP) is a collaborative effort to define a comprehensive set of diabetes process and outcome measures for national adoption.^{3,4} Sponsoring organizations include the American Diabetes Association, the National Committee for Quality Assurance, the Foundation for Accountability, the Health Care Financing Administration, the American College of Physicians, the American Academy of Family Physicians, and the Veterans Administration. It is expected that these sponsoring organizations will promulgate the use of these measures among their constituencies. Sheldon Greenfield, MD, of the New England Medical Center, serves as the Chair.

There are three categories of measures in the initial set: 1) the accountability set; 2) the quality improvement set; and 3) patient-reported measures. The accountability set includes the

measures that are ready for public reporting. The quality improvement set includes measures that can be used for internal quality improvement efforts but are not ready for public reporting. The patient-reported measures still require field testing.

The accountability set includes: 1) annual glycosylated hemoglobin testing; 2) patients with glycosylated hemoglobin levels greater than 9.5%; 3) annual screening for microalbuminuria; 4) LDL testing in the last 2 years; 5) patients with LDL less than 130 mg/dl; 6) patients with blood pressure less than 140/90; 7) dilated eye exam in the last two years; and 8) foot exam in the last year.

The quality improvement set includes: 1) glycosylated hemoglobin control distribution; 2) lipid control distribution; 3) blood pressure distribution; and 4) documented comprehensive foot exam. Patient-reported measures on: 1) education and self-care; 2) satisfaction with, and access to care; 3) coping/functional status; and 4) lost time from daily activities.

RHODE ISLAND QUALITY PARTNERS: QUALITY IMPROVEMENT PROJECTS

Two quality improvement projects are underway. They focus on prevention of chronic, not acute complications of diabetes mellitus. This issue of *Medicine and Health / Rhode Island* is part of our collaborative intervention on the two current projects.

a) fee for service beneficiaries

The long term goal of this project is to decrease blindness due to diabetic retinopathy in fee-for-service beneficiaries. The short term goal is to increase screening for retinopathy before the disease becomes symptomatic. Early this year, beneficiaries with diabetes mellitus received post-cards reminding them of the benefits of dilated eye exams and pointing out that the service is covered by Medicare. Primary care physicians and eye care professionals received copies of this mailing along with an endorsement by physician leaders in the state. In mid-year, office kits were distributed to physicians' offices for display in waiting rooms. These displays were designed to raise patients' awareness about eye exams prior to their scheduled visits. Primary care physicians were also given contact information for participating eye care professionals to facilitate referral. Eye care professionals were asked to complete the communication loop by sharing the results of screening with the referring physician. RIQP is currently counting the bills for dilated eye exams and will compare these numbers to those in the same months of the previous year.

b) managed care beneficiaries

The goal of this project is to increase the provision of a variety of preventive services to Medicare beneficiaries in managed care plans. These services include dilated fundus-copic exams, glycosylated hemoglobin testing, office visits, foot exams, nephropathy screening, dyslipidemia screening, and the treatment of important comorbidities and complications. RIQP will be abstracting data from office charts when this article comes to print. The performance data will be shared with the participating plans so that improvement



efforts can be designed to meet specific needs. We anticipate that there will be substantial room for improvement based upon previous studies in Rhode Island and in other states.

The Health Care Financing Administration has identified diabetes as an important condition for the next Peer Review Organizations' contract cycle. RIQP will be developing additional diabetes projects for this next scope of work. Look for updates in the monthly column, "Health Care Quality Improvement in Rhode Island."

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4. www.diabetes.org/dqip.htm
5. www.niddk.nih.gov/health/diabetes/ndep/ndep.htm
6. www.diabetes.org/medicare

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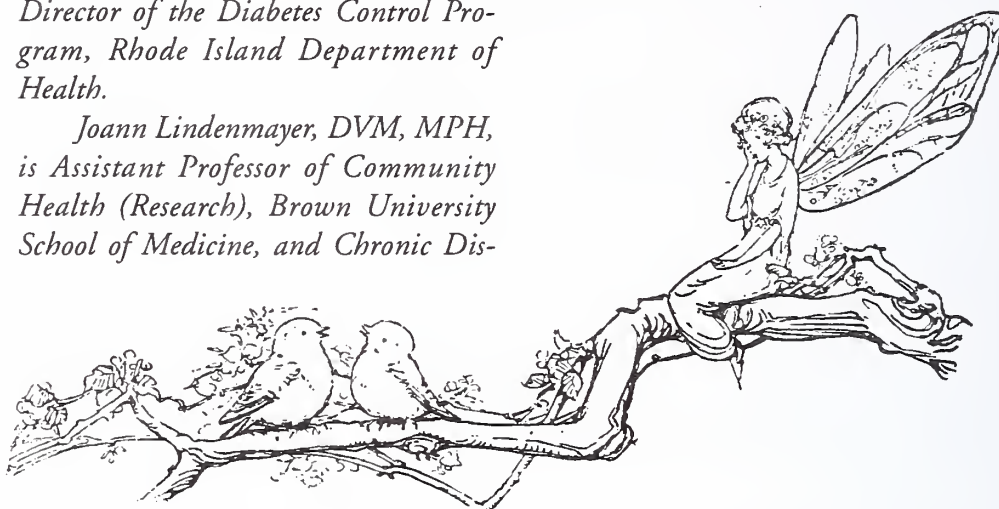
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Diabetes Case Study from a Primary Care Perspective

Ray Maxim, MD

For a primary care provider few patients can be more demanding and challenging than the diabetic patient. The very nature of the disease, with its multiple organ system involvement and the indolent disease process, makes management difficult and time-consuming. Patient involvement in their disease management plays a much more vital role in the success, or failure, of the treatment plan when compared to most other disease entities that we treat. It is frequently difficult to convince patients of the serious nature of their disease until they have experienced a late complication. Diabetes becomes more of an immediate priority when a person's vision begins to fail, or the patient is hospitalized with a diabetic foot ulcer.

Therefore it is imperative that intensive patient education begin early in the course of disease. Just as important is introducing the patient to the resources available to help them manage their disease. This can be accomplished by a referral to the Diabetes Foundation of Rhode Island or the American Diabetes Association. In addition a few of the managed care organizations have terrific materials for diabetic patients. Glucose monitoring equipment is available to most patients. Coverage of diabetes-related materials has improved with recent changes in Medicare benefits. Just as important as the patient's involvement is the provider investment in education, monitoring and treatment. Your patient may have

Abbreviations Used:

ACE angiotensin converting enzyme

spent many hours with a dietitian or diabetes educator, but if you do not reinforce that education, the patient is less likely to think it important enough to act upon. A few words about diet, the long-term consequences of poorly controlled disease, or some other aspect of diabetes care pertinent to that individual patient during each visit demonstrates commitment to your patient's life-long education.

One theme underlying much of today's medical literature is that treatment of disease needs to be patient-spe-

cific as well as disease-specific. An example would be the diabetic with hypertension and nephropathy who may be better served by treatment with an angiotensin converting enzyme (ACE) inhibitor rather than beta blockers or diuretics. For clinicians the concept that some patients are subtly and sometimes dramatically different and require a different approach is not new. However there are aspects of diabetes care that are fundamental to the care of most patients. Monitoring fasting blood sugars and glycosylated hemoglobin are essential to gauging the degree of glucose control. Sharing the numbers with the patient not only provides the patient with a personal yardstick for their compliance and degree of control, it also reinforces the long time nature of the battle with diabetes. Management of comorbidities especially hyperlipidemia, hypertension, and obesity takes on a more urgent nature in the diabetic patient. As a consequence special attention should be paid to the lipid profile and a more aggressive attempt to reach the target low density lipoprotein goals as suggested by the National Cholesterol Education Program guidelines is warranted. Blood pressure control should vigorously attempt to reach the target blood pressure levels suggested by Joint National Commission on Detection, Evaluation and Treatment of High Blood Pressure VI guidelines.

Weight control is an especially difficult problem as not only does diabetes lead to weight gain, most of the glucose-lowering agents tend to exacerbate weight problems. Both patient and physician commitment to a regular exercise program and diet (for the patient that is, though we probably should heed our own advice) is needed for any meaningful progress. Having information available in the office about specific programs is helpful. Most programs will be more than happy to provide literature for your office. These include everything from personal trainers to the local YMCA. Some patients will need direction because of specific limitations. Those with arthritis or significant weight problems should be directed to low impact programs or preferably to pool exercise programs. All should be

advised to diversify their program as boredom with a single activity can lead to failure. Contingencies should be made for seasonal changes. A successful summer walking program will likely stall during the winter, losing any benefits gained.

In concert with the management of the glucose and comorbid disease is the monitoring of disease progression. Evaluation for the presence or the progression of renal disease with microalbuminuria testing or quantitative proteinuria is mandatory for most patients not on dialysis. At least yearly dilated funduscopy exams can head off retinopathy, the most common cause of blindness in this country. Finally, regular documentation of a thorough foot examination to monitor for both occult infection and progression of neuropathy can prevent unnecessary hospitalizations or falls. This should be followed by instruction on daily self exams of both feet. A strategically placed mirror can make it easier for those patients with difficulty seeing the bottom of their feet because of limited mobility. A podiatry referral would be appropriate in those with existing neuropathy or those with established foot disease.

CASE STUDY:

Mrs. H is a 65 year old who has not seen a physician since the birth of her last child 40 years ago. She is referred to you by the a local nursing agency after a diabetes screening clinic found an elevated blood sugar. She arrives at your office with a slip of paper that states her blood sugar was 220 and her cholesterol was 290. Your history reveals that she had fasted prior to the screening on advice from a family member. When you asked her why she had decided to attend the diabetes screening she said "because I have been feeling tired a lot and my mother and sister both have sugar." Upon further questioning she reveals that she has symptoms of polyuria, polydipsia and she tells you that she has gained 20 pounds over the last year. She denies chest pain but does admit to becoming short of breath when she walks for more than 5 minutes or she has to climb more than one flight of stairs. The rest of her past medical is

unremarkable. Her family history in addition to diabetes is notable for coronary artery disease. Her father died at age 55 from a myocardial infarction and her brother had a coronary artery bypass at age 61. A review of her social history is remarkable for the absence of tobacco use and only rare alcohol at special occasions. She is a retired jewelry worker with no history of toxic exposures. She currently lives alone in senior housing since the death of her husband 2 years ago. She is able to maintain her home and finances and utilizes the bus to take her to the local senior center to see her friends and to do her shopping.

Physical Exam: BP 154/90, P 86, R 16, Ht. 5' 2", Wt. 186 lb.

Mrs. H is a well groomed obese woman in no particular distress. HEENT is notable for immature cataracts that limit your evaluation of her fundi. Her neck is large but there is no evidence of JVD, adenopathy or thyromegaly. Her carotid pulses are 1+ and there is an absence of bruits. Her lungs are clear and her apical pulse is 80 and regular. No murmur or gallop is detected. Breast exam is normal. The abdomen is obese bowel sounds are present and liver and spleen appear to be of normal size. No abdominal bruits are noted. Pelvic and rectal exams are normal. Examination of the lower extremities is remarkable for diminished posterior tibial and dorsalis pedis pulses and the absence of hair on both feet. Neurological evaluation is unremarkable except for decreased vibratory and position sense. Additionally, there is also a decrease in sensation to touch as demonstrated by a monofilament.

LAB:

You are able to do a fingerstick blood sugar that reveals a 3 hour post-prandial blood glucose of 305. A dipstick urinalysis is normal except for 2+ glucose. Proteinuria is not present on dipstick.

DISCUSSION: How do we address this patient's needs?

With a fasting blood glucose of 220 and a random blood sugar of 305 the likelihood of diabetes is high according to American Diabetes Association criteria. Documentation of a fasting glu-

cose and HgA1C would be appropriate. Most physicians would elect to treat based on these numbers, though some would elect to get that second FBS to document diabetes. The treatment can vary, but a sulfonylurea is a reasonable first step though initial monotherapy with metformin may be a better choice. At this time an effort to explain the nature of diabetes and its treatment is important. It is the rare patient who can comprehend it all at least in the beginning, but emphasis of the patient's involvement in learning is essential. At this time it would be appropriate to supply the patient with a glucometer. Most companies will provide your office with machines to give patients. Your office nurse can explain its use but most patients will not feel comfortable immediately testing their own blood sugars. We usually schedule them back for diabetes teaching the next week at a time when the office is not seeing patients. When the patient leaves the office after the initial appointment, she will have not only her follow-up appointment and education session and glucometer, she will have a referral to the RI Diabetes foundation.

The next issue to be addressed is hypertension. A single elevated blood pressure reading is not adequate to diagnose hypertension. A follow up reading during the education session would be reasonable. The decision to treat can be delayed to give diet and exercise an opportunity to work. However the presence of proteinuria would signal the need to treat earlier. The agent of choice is an ACE inhibitor because of the potential for renal protective effects in addition to the antihypertensive action. Angiotensin II receptor antagonists and calcium channel blockers may also have some protective effect but the preponderance of evidence favors the ACE inhibitor class at this time. Treatment goals should be for a systolic pressure of 120 mmHG.

Hyperlipidemia contributes to the progression of coronary artery disease that is so prevalent in diabetics. This patient certainly has elevated total cholesterol if the screening test was truly fasting. For the sake of this article we will assume that it is a fasting reading.

A lipid profile to determine the severity and phenotype will help determine the next course of action. Special attention to the triglyceride levels is needed as hypertriglyceridemia may determine the lipid lowering agent you choose if dietary methods fail.

Those with arthritis or significant weight problems should be directed to low impact programs or preferably to pool exercise programs.



Disease progression monitoring in the form of dilated eye exams is essential. The patient should leave the office with an appointment with an eye care professional. It is important to document these exams for future reference. In addition to eye exams measurement of microalbumin or a quantitative urine protein measurement should be done at least yearly. In this case a microalbumin level would be reasonable as there was no protein detected by dipstick. If the microalbumin is greater than 20 initiation of ACE inhibitor therapy is indicated. Another item to be monitored is a foot exam to evaluate for the presence of neuropathy and observe for signs of infection. As a general rule all diabetic patients should have their shoes removed when they enter the exam room before the physician even enters the room. In a busy practice a foot exam is much more likely to be done when the shoes are already removed.

Our fictional patient is overweight. Complimenting the dietary advice by your diabetes educator or dietitian should be an exercise program to help her lose weight and reduce her insulin resistance. Mrs. H unfortunately tells us that she has significant family history of heart disease. She also complains of some exercise intolerance. Even in the face of a normal ECG it would be difficult to recommend that she join the local gym without some degree of

evaluation. An exercise tolerance test before developing any program for Mrs. H would seem a wise move. It will also help you gauge the intensity of any exercise prescription you give to this patient.

This is one example of how we can manage the diabetic patient. The comments are a compilation of my own practice patterns and discussion with colleagues about how they manage their patients. It is by no means the authority but hopefully will serve as a focus for discussion and reflection on our current practice patterns. We live in an exciting time in medicine where we can do more for our patients than ever before. Unfortunately, it can take many years for proven interventions to enter daily practice. For us to improve as a profession we must strive not only to improve on existing knowledge but also to put into practice what we already know. Sharing practice patterns that work will help us reach that goal.

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Resources for Persons with Diabetes

Diabetes Foundation of Rhode Island

1007 Waterman Avenue
East Providence, Rhode Island 02914
(401) 431-1900

Office hours: Monday thru Friday; 8:30 a.m. - 5:00 p.m.

The Diabetes Foundation of Rhode Island provides patient and professional education programs and supports funding for research. The Foundation provides daily support groups throughout the state and participates in community service and outreach programs for people with diabetes and their families. A special support group for parents of children with diabetes is also available. Camper scholarships are awarded each spring to allow children to attend diabetes camps. The Diabetes Foundation is an excellent source for printed information and referrals.

Diabetes Control Program

Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908
(401) 222-3442

Office hours: Monday thru Friday 8:30 a.m. - 4:30 p.m.

The Diabetes Control Program (DCP) certifies diabetes educator programs and its educators and coordinates diabetes outpatient education programs throughout the state. The DCP works with many health care agencies and providers to address issues related to diabetes care policy, quality assurance, surveillance, and patient and professional education. In addition, the DCP is a resource for information on diabetes, diabetes activities and services in the state.

Diabetes Education Services

Sites include:

Associates in Nutrition	944 - 5703
Cardiology Associates, Inc.	766 - 5959
Diabetes Education Services	737 - 3415
	884 - 0373
Diabetes and Endocrinology Associates	351 - 7100
Harvard Pilgrim Health Care of N.E.	331 - 4034
	x43390
Insight	941 - 3322
Kent Hospital Diabetes Management Center	737 - 7010
Landmark Medical Center and	
Landmark Heart Center	769 - 9355
Memorial Hospital of RI	729 - 2503
Miriam Hospital	331 - 8500
	x 33634
Newport Naval Hospital	843 - 1275
Northwest Health Center	567 - 0800
Our Lady of Fatima	456 - 3000
Providence Ambulatory Health Care Foundation	444 - 0400
Rhode Island Hospital	444 - 4778
St. Joseph Center for Health and Human Services	456 - 4419
South County Hospital	782 - 8020
	x 159

VNA of Rhode Island	444 - 9400
VNS Home Care	1 - 800 - 834 - 3334
	788 - 2265
Westerly Hospital	596 - 6000
	348 - 3282
Women and Infants Hospital	274 - 1122
	x 1532

The Diabetes Outpatient Education (DOE) program provides 12 hours of group education or one-to-one individual sessions by certified health professionals: nurses, dietitians, and pharmacists.

RI Nutrition Information Center

Nutrition Hotline
RI Department of Health
3 Capitol Hill
Providence, RI 02908
1-800-624-2700 (toll free)
Monday, Wednesday, Friday; 9:00 a.m. - 1:00 p.m.

The Hot Line nutritionist provides information about healthy foods, as well as printed materials and referrals about particular nutritional needs.

IN-SIGHT

43 Jefferson Boulevard
Warwick, RI 02888
(401) 941-3322
Office hours: 8:30 a.m. - 4:30 p.m.

IN-SIGHT re-orientes persons who are blind and visually-impaired, showing them how to rely on their other senses to perform daily tasks, learn new skills, enjoy their hobbies, and earn a living. Client fees are on a sliding scale. A special independent living service for people with diabetes offers individual counseling, peer support groups, instruction in health management, diet and medication.

Rhode Island Services for the Blind and Visually Impaired

40 Fountain Street
Providence, RI 02903
(401) 277-2300
TDD: (401) 277-3010
Office hours: Monday thru Friday 8:30 a.m. - 4:30 p.m.

This agency serves Rhode Islanders who are blind or visually impaired. Services, provided statewide, include counseling, assessment, vocationally-related training, job development and placement, social services, family casework, rehabilitation teaching, orientation and mobility, independent living and adaptive equipment. Most services are provided free of charge.

Ocean State Center for Independent Living

59 West Shore Road
Warwick, RI 02889
(401) 738-1013
TDD: (401) 738-1015
Office hours: Monday thru Friday 8:30 a.m. - 4:30 p.m.

This agency provides an initial assessment to plan independent living goals, leading to instruction in developing skills to live independently: communication, education and training, employment, equipment, finances, nutrition, self-care, transportation and recreation. Peer support groups are a vital part of the Center's mission.

National Insurance Consumer Helpline

1-800-942-4242 (toll free)

The Health Insurance Association of America, the American Council on Life Insurance, and the Insurance Information Institute run a hotline which can provide general information on health insurance, and field complaints about particular companies.

Diabetes Resource Center

St. Joseph Center for Health and Human Services
21 Peace Street
Providence, RI
(401) 456-4313

Office hours: Monday thru Friday 8:00 a.m. - 4:00 p.m.

The Diabetes Resource Center (DRC) provides resources for persons who have immediate diabetes-related health needs, and assists with access to long-term health care and diabetes education. Diabetes medications and supplies (for 30 days) are provided for patients. To be eligible, the person needs to have limited resources or be under or uninsured and referred by a community agency or be served by one of the DRC health care providers. Participating providers include: St. Joseph Center for Health and Human Services, Providence Ambulatory Health Care Foundation, Rhode Island Hospital, Medical Primary Care, Traveler's Aid Society, and Blackstone Valley Health Centers. The sites are especially helpful for bilingual and bicultural patients. DRC services are available at no cost.

Visiting Nurse Associations, Home Health Associations

Services available 24 hours per day 7 days per week, multilingual

Visiting nurse and home health associations offer diabetes education, nutrition counseling, and treatment of diabetes complications for homebound patients. Home visits are based on doctors' orders. Persons with diabetes or their families can request services or information by calling one of many agencies throughout the state. Agencies will investigate third party eligibility for services. Under specific circumstances, Medicare, Medical Assistance, and commercial providers will cover home diabetes services.

DIABETES CAMPS

Clara Barton Diabetes Center

P.O. Box 356
North Oxford, Massachusetts 01537
(508) 987-2056

The Clara Barton Diabetes Center operates the Clara Barton Camp. This camp offers a summer camp for girls age 6-16, an Adventure Camp, and year-round Family Support Weekends. The Center offers scholarships on a first-come, sliding scale basis.

Joslin Diabetes Center

Camp Office
1 Joslin Place
Boston, Massachusetts 02215
(617) 732-2455

The Joslin Diabetes Center operates the Joslin Camp for boys with diabetes. The sessions vary in length and the Joslin Center offers scholarships on a sliding scale basis.

ADDITIONAL HEALTH RESOURCES

1. **American Diabetes Association**
1660 Duke Street
Alexandria, VA 22314
1-800-DIABETES
www.diabetes.org/ada/prpqa.htm
2. **National Heart, Lung, and Blood Institute Information Center**
P.O. Box 30105
Bethesda, Maryland 20824-0105
(301) 251-1222
1-800-575-WELL (toll free)
3. **American Heart Association**
Rhode Island Affiliate
40 Broad Street
Pawtucket, RI 02860
(401) 728-5300
4. **American Lung Association of RI**
10 Abbott Park Place
Providence, RI 02903
(401) 421-6487
5. **Centers for Disease Control and Prevention (CDC)**
National Centers for Chronic Disease Prevention and Health Promotion
Division of Nutrition and Physical Activity
4770 Buford Highway, NE, Mailstop K-46
Atlanta, Georgia 30341
1-888-232-4674 (toll free)
[Http://www.cdc.gov](http://www.cdc.gov)
6. **Weight Control Information Network**
1 Win Way
Bethesda, Maryland 20892-3665
(301) 570-2117
1-800-946-8098 (toll free)
WIN@matthewsgroup.com
7. **National Diabetes Education Program**
Division of Diabetes Translation
CDC
(770) 488-5037
www.cdc.gov/diabetes



Estimates of Diabetes in Rhode Island: A Moving Target

Joann M. Lindenmayer, DVM, MPH

An estimated 16 million Americans have diabetes mellitus (types 1 and 2); one-third are unaware of it.¹ Its prevalence has increased three-fold since 1958 and is likely to increase further as the prevalence of obesity increases, the population ages, minority populations grow, and a socioeconomic gap persists.² The recently revised guidelines for diagnosis are expected to be reflected in increasing prevalence of the disease.³

Approximately 50,000 Rhode Islanders over age 18 have the disease.

The State Surveys

There are two primary sources for Rhode Island-specific estimates of the number of Rhode Islanders with diabetes: the Behavioral Risk Factor Surveillance System (BRFSS) and the Rhode Island Health Interview Survey (RIHIS).

The BRFSS is an ongoing, random digit-dial, statewide telephone survey of adult residents conducted as a cooperative effort between the Centers for Disease Control and Prevention (CDC) and state health departments. In 1996, interviews were conducted with 2,482 adult Rhode Islanders. All were asked, "Have you ever been told by a doctor

that you have diabetes?" A minority oversample was conducted in addition to the statewide sample. A person with diabetes was defined as anyone who answered "yes," excluding women who were told they had diabetes only during pregnancy. The prevalence of diabetes (Figure 1) was calculated using weighted estimates of the number of persons with diabetes divided by the weighted number of respondents, expressed as a percentage. Responses were weighted to the population of Rhode Island. The prevalence of diabetes for Rhode Island and for population subgroups was calculated only for groups with at least 50 (unweighted) respondents.

Estimates of the actual number of people with diabetes in Rhode Island, and in population subgroups, were calculated from the weighted estimates of the number of people 18 years of age and over in the population. Estimates of prevalence and numbers of people were increased by a factor of 1.5 because the Third National Health and Nutrition Examination Survey (NHANES III) indicated that persons diagnosed represented two-thirds of all persons with diabetes. (Figure 2).

The RIHIS is a random digit-dial, statewide telephone survey of household residents that is conducted every five years. In 1996, information was collected on 6,578 Rhode Island residents. In each household, the adult identified as the person most knowledgeable about the health and medical care of the people living there was asked, "Have you/has anyone in the household ever been told by a doctor that you/they had diabetes, sugar in their urine, or high blood sugar?" As with the 1996 BRFSS, a minority oversample was conducted. The definition of diabetes was the same as that used for the BRFSS, and persons younger than 18 years of age were excluded from the analysis. The prevalence of diabetes (Figure 1) was calculated using weighted estimates of the number of persons with diabetes divided by the weighted number of respondents, expressed as a percentage. Responses were weighted to the sample. As with the BRFSS, prevalence for Rhode Island and for population subgroups was calculated only for groups with at least 50 (unweighted) respondents.

Estimates of the actual number of people with diabetes in Rhode Island, and in subgroups, were calculated from the RIHIS using the weighted estimates of

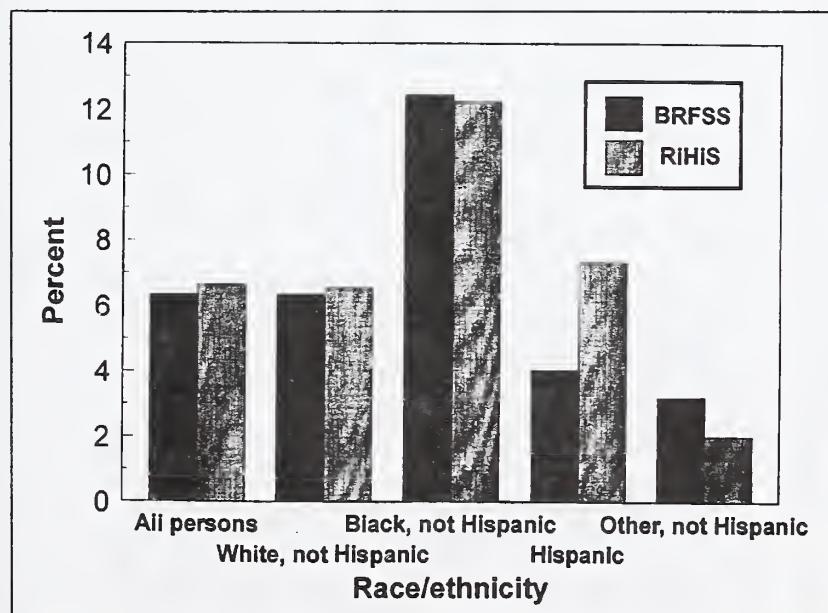


Figure 1. Adjusted prevalence of diabetes in Rhode Island by race/ethnic group, as measured by the 1996 Behavioral Risk Factor Surveillance System (BRFSS) and the 1996 Rhode Island Health Interview Survey (RIHIS).

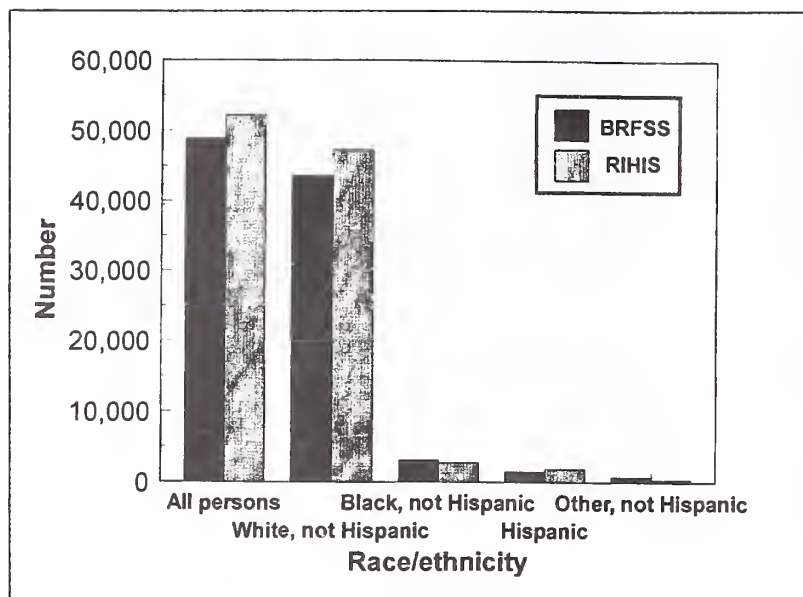


Figure 2. Adjusted estimates of the number of persons in Rhode Island with diabetes by race/ethnic group, as measured by the 1996 Behavioral Risk Factor Surveillance System (BRFSS) and the 1996 Rhode Island Health Interview Survey (RIHIS).

the number of people with diabetes in the sample, multiplied by the factor $754,254/4,671$ (the estimated number of Rhode Islanders 18 years of age and over in 1996, divided by the number of RIHIS respondents 18 years of age and over). Estimates of prevalence and numbers were adjusted as previously described. (Figure 2).

Results

Regardless of which survey is used, the prevalence of diabetes is highest among persons who are Black, not Hispanic. The prevalence of diabetes in subgroups is comparable on both surveys except that the prevalence of diabetes

among persons of Hispanic ethnicity on the RIHIS is nearly twice the prevalence estimated by the BRFSS.

Persons who are white, not Hispanic, constitute the largest subgroup with diabetes, followed by persons who are Black, not Hispanic, and by persons who are Hispanic.

The surveys show that about 50,000 Rhode island adults are at risk for serious complications and premature death from diabetes. Early identification and best practice medical management can reduce these risks, adding quality years to the lives of the people with diabetes.

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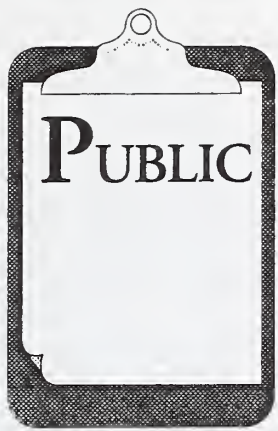
The author is grateful to Ms. Janice Fontes, Office of Health Statistics, the Rhode Island Department of Health, for technical assistance.

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PUBLIC

HEALTH BRIEFING

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by John P. Fulton, PhD

Preview: Lyme Disease Vaccines

Edward F. Donnelly, RN, MPH

Two companies, SmithKline Beecham Pharmaceuticals and Pasteur Mérieux Connaught, have developed and tested vaccines against infection with *Borrelia burgdorferi*, the causative organism of Lyme disease. The SmithKline Beecham product was recommended for approval by the Vaccine and Related Biological Products Advisory Committee of the US Food and Drug Administration in May. The Pasteur Mérieux Connaught product began efficacy testing a bit later and has not yet been approved by the Committee. The two products are essentially the same.

BACKGROUND

Lyme disease is caused by infection with the spirochete *Borrelia burgdorferi* transmitted by the bite of *Ixodes scapularis*, the deer tick. The white-footed mouse, *Peromyscus leucopus*, is the reservoir for the infection. The larval tick hatches from an egg in the Spring and often obtains a first blood meal from an infected mouse. The tick drops from the reservoir host, molts, and overwinters as a nymph. During May through July, in the second year of life, the infected nymph seeks a blood meal from a mouse, bird, other small mammals, or such accidental hosts as dogs and humans. The nymph requires several days of attachment to complete the meal. The spiro-

Abbreviations Used:

CDC	Centers for Disease Control and Prevention
DEET	N,N-diethyl-3-methylbenzamide
OSP A	outer surface lipoprotein A

chete, which has lain dormant in the gut of the tick, is activated by the in-flow of blood and migrates through the hemocele to the salivary gland of the vector from which it enters the new host. Studies in the golden hamster [or animal model] show that transmission does not occur in the first twenty-four hours of attachment. After forty-eight hours, 50% of experimental animals are infected and 100% are infected after seventy-two hours of attachment. Sexual differentiation occurs during the molt to the adult form. Adult females seek a third blood meal from October to April, most commonly from the white-tailed deer, the reproductive host. Adult males seek a mate on the host, where mating occurs while the female is feeding. Adult males do not feed on blood or transmit borellia.

In Rhode Island, deer ticks can be found in deciduous woodlands throughout the state, with a concentration in Washington County and islands of Narragansett Bay. Annual tick surveys conducted by entomologists at the University of Rhode

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Island show considerable year-to-year variability but suggest an expansion inland. There are relatively few deer ticks in northwestern Rhode Island and in Bristol and Newport Counties with the exception of Prudence and Patience islands, where deer ticks have always been common, and the town of Jamestown where increases have been noted in recent years.

Approximately 19,000 cases of Lyme disease were reported last year to the Centers for Disease Control and Prevention (CDC) by state health departments. The distribution is regional with concentrations on the Eastern Seaboard from Massachusetts to Maryland, in the North Central States of Wisconsin and Minnesota, and on the Pacific Coast from Northern California to Oregon. Increased surveillance and greater awareness among physicians and the public have led to increased case reporting in recent years. Place of residence is a risk factor for Lyme disease in Rhode Island as has been shown elsewhere. In many years, 70% or more of reported cases resided in Washington County, home to only 11% of the population of the State.

Control efforts have emphasized individual knowledge and behavior, including avoiding tick habitat, wearing protective clothing, the use of insect repellents containing DEET, and daily inspections for deer ticks after being in tick habitat. Secondary prevention involves the recognition of the seasonality of Lyme disease and early symptoms that include a pathognomonic, expanding skin rash, fever and pain in head, neck and other joints. Early infection is almost always effectively treated with a three week course of common antibiotics such as Doxycycline in adults and Amoxicillin in children and pregnant or lactating women.

NEW LYME DISEASE VACCINES

The vaccines offered by SmithKline Beecham and Connaught are composed of a recombinant DNA-produced outer surface lipoprotein called OSP A and aluminum hydroxide. This antigen is not expressed in the host but in the gut of the vector. Circulating antibodies in the blood of an immunized host contact and bind with the antigen when it is ingested. Thus, the effectiveness of the vaccine depends on maintenance of high levels of circulating antibody in the vaccinee. High levels were demonstrated in the study subjects after the third dose.

Most of the study subjects were recruited in the New England and Mid-Atlantic States. The SmithKline Beecham trial included 10,936 subjects; the Connaught trial, 10,305. Vaccine efficacy was computed as 76% by SmithKline Beecham and 92% by Connaught after three doses. There may be some lower immune response and lower efficacy in those over 60 years of age.

Study subjects were given vaccine or placebo at month 0, 1, and 12. This is considered a difficult schedule. Studies are planned to determine if the long delay between injection two and three are necessary and if it is possible to modify the three-injection schedule to 0, 1 and 6 months. Follow-up is being conducted on subjects who received vaccine to determine the need for booster doses. There was some reduced immunogenicity in older males in the SmithKline Beecham study although other age or gender differences were not found. Vaccination was associated with redness and soreness at the site of the injection in a quarter of subjects who received vaccine and with fever, chills, and malaise that lasted a median of three days in

Recommendations for the Lyme disease vaccination program are as yet unofficial but would resemble those for influenza.



about 2% of vaccinees.

DISCUSSION

Vaccination against infectious diseases is one of the most efficient and successful public health interventions of the 20th century. The extinction of smallpox, the disappearance of polio from the western hemisphere, and the near elimination of measles from the United States are all accomplishments of immunization programs. Each of these is a viral illness, transmitted person to person, whose reservoir is man. The new Lyme disease vaccines target a bacterial disease that is transmitted by a tick vector, has a rodent reservoir, and a cycle in nature that is not dependent on producing human cases. There are a number of limitations to the benefits of the vaccine:

- The study schedule causes a delay in initial immunity and may produce difficulties in follow-up for completion of the series.
- There will be a need for booster doses, as with other vaccines against bacterial pathogens.
- Vaccination of well-educated, influential residents of endemic areas may reduce support for tick control and other environmental measures that can be effective against all tick-borne diseases.
- A reduced vigilance for ticks may increase risk for other tick-borne diseases that are not prevented by the vaccine.
- This vaccine produces no herd immunity and even widespread vaccination would do nothing to reduce the risk to the unvaccinated.

Recommendations for the Lyme disease vaccination program are as yet unofficial but would resemble those for influenza. Groups at high risk for the disease and its complications would benefit from the vaccine. The vaccine will also be recommended for others who wish to reduce their risk of contracting Lyme disease. The groups at high risk are:

- residents of hyperendemic areas
- those with high degree of occupational or recreation exposure in endemic areas
- visitors to hyperendemic areas

There will certainly be considerable demand for the vaccines in Rhode Island. Public anxiety over Lyme disease has been high and the general press has given it a great deal of attention. Many people say they have avoided healthful outdoor activities for fear of Lyme disease. Because there is such high risk in some parts of the State, medical providers may consider reduction in anxiety to be sufficient indication for vaccination in some of their patients. It is not known if the cost of the new vaccines will be covered by third party payers.

Because the vaccine is well under 100% effective, some patients who have been vaccinated will develop Lyme disease. It is important to note that standard ELISA and similar serologic tests will register a positive result due to the vaccine. Serologic tests in suspected cases of Lyme disease who have been vaccinated should be performed by Western blot, as was done in the vaccine trials. This test has been previously recommended by CDC as a confirmatory test after a positive or equivocal ELISA. Expect the vaccine-induced 31- kd band to be reported in the immunized patients.

SUMMARY

Lyme disease is a tick-borne spirochetal disease that is common in Rhode Island. The OSP A based vaccine against Lyme disease that has been shown effective in animal models has now been tested by two manufacturers in thousands of people. The vaccines appear to be safe and effective. When the vaccines become available to physicians, there should be strong demand in Rhode Island, especially in the southern part of the State where there is a high degree of public awareness and experience with Lyme disease. Studies of tick populations support surveillance data that show a concentration of risk in Washington County with a trend of expansion inland. Patients who receive the vaccine should be alerted to the likelihood of local reaction and the less likely systemic effects. Additional patient education should include awareness of other tick-borne diseases such as babesiosis, ehrlichiosis, and Rocky Mountain Spotted Fever that are not vaccine-preventable. Serologic testing for Lyme disease will be affected by the immune response to the vaccine. These vaccines have not yet been tested in children.

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Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	May 1998	12 Months Ending with May 1998	
	Number	Number	Rates
Live Births	1,066	13,202	13.3*
Deaths	722	9,806	9.9*
Infant Deaths	(5)	(97)	7.3#
Neonatal deaths	(2)	(75)	5.7#
Marriages	829	7,679	7.8*
Divorces	341	3,311	3.3*
Induced Terminations	310	4,924	373.0#
Spontaneous Fetal Deaths	116	972	73.6#
Under 20 weeks gestation	(106)	(900)	68.2#
20+ weeks gestation	(10)	(72)	5.5#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	November 1997	12 Months Ending with November 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	279	3,313	334.6	3,701.5
Malignant Neoplasms	223	2,486	251.1	7,232.5
Cerebrovascular Diseases	57	712	71.9	820.0
Injuries (Accident/Suicide/Homicide)	28	333	33.6	6,610.5**
COPD	33	453	45.7	330.0***

**Excludes two deaths of unknown age

***Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.



Judicial Diagnosis

Tarasoff: Duty to Warn? Duty to Protect?

Cynthia J. Warren, JD

The expression "between a rock and a hard place" comes to mind. Physicians and mental health providers may find themselves caught between a duty to preserve their patients' confidential information and a duty to warn potential victims of violent threats made by those patients. A misstep, in either direction, exposes the provider to liability, either to his/her patient for breach of confidentiality or to the victim or victim's family for injuries resulting from the provider's failure to warn or to take other measures to protect the victim from harm.

The seminal case, decided twenty-five years ago, is *Tarasoff v. Board of Regents*. Although Rhode Island courts have not yet interpreted any *Tarasoff*-like cases, the state legislature, in the confidentiality statute (the "Confidentiality Act"), anticipated their inevitability. Under that statute, "health care providers" may disclose otherwise confidential patient information to law enforcement personnel or to a particular individual if the provider believes that the individual or his/her family may be endangered by the patient. Because the Rhode Island courts have not interpreted this provision of the Confidentiality Act or more generally dealt with *Tarasoff*-like situations, physicians must seek guidance from other jurisdictions. It could be a costly mistake for physicians to conclude that the absence of local judicial interpretation eliminates their duty to potential victims, as there is little question that such a duty exists.

Tarasoff cases essentially are negligence claims, where a plaintiff must prove: (i) that the practitioner owed a duty of care to the injured person; (ii) that the practitioner breached that duty by failing to take proper actions to prevent the injury; and (iii) that the injury resulted from the practitioner's failure to act. Because courts have concluded that the last element is proven upon proof of the first two, this article focuses on the first two elements: to whom practitioners owe this duty and the actions required to discharge this duty.

Generally, the law does not require a person to control anyone else's conduct or to protect those who are endangered by another person's conduct. An exception to the "no duty" rule arises, however, out of the special relationship between physicians and patients, and the not always well-founded belief that a physician can control not only the patient's illness, but the patient's conduct as well.

Accordingly, not only does the physician owe a duty of care to his patients but he/she also is obligated to take "reasonable steps" to control his/her patient to avoid harm to others. Most typically, this duty arises when a physician treats a patient for a contagious disease. In this instance, "reasonable steps" will depend upon the professional standard of care relating to that disease, as well as any governing statutes. The *Tarasoff* Court, using a similar rationale, concluded that a practitioner owes a duty of care to avoid harm to his/her patient's potential victims.

The facts of *Tarasoff* are these. During therapy, a patient told a University of California psychologist that he planned to kill an unnamed young woman. The psychologist asked campus police to transport the patient to a psychiatric hospital for involuntary civil

commitment. The campus police detained and released the patient after he promised to stay away from the woman. The psychologist took no more action. Two months later the patient killed the woman.

The victim's parents sued the psychologist and the University of California, alleging that the psychologist should have warned their daughter of the patient's violent threats and should have detained the patient by involuntary civil commitment.

In the so-called *Tarasoff I* case, the California Supreme Court concluded that once a therapist determines, or "under applicable professional standards" should have determined, that a patient poses a serious danger of violence to others, the therapist must exercise reasonable care to protect the foreseeable victim. In *Tarasoff I*, the Court explained that the "foreseeable victim" must be "readily identifiable." Although the patient did not name his prospective victim to the psychologist, her name could be discerned upon "a moment's reflection;" therefore, the woman was a "foreseeable victim." The Court concluded that the psychologist should have warned Ms. Tarasoff and/or her family, and that the psychologist's failure to warn prevented the family from protecting their daughter. The Court concluded that this failure caused Ms. Tarasoff's death. The Court, however, rejected the claim that the psycholo-



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gist was liable for failing to detain his patient, reasoning that voluntary commitments are discretionary.

In 1976, the California Supreme Court granted a rehearing at the request of several professional organizations which sought clarification of the duty to warn. In the so-called *Tarasoff II* case, the Court, finding that the duty to warn often was ineffective, ruled that there was a more expansive duty to protect "identifiable, endangered victims." *Tarasoff II* required therapists to discharge their duty not only by warning potential victims but also by "taking whatever other steps are reasonably necessary to protect potential victims." Commentators have noted that the *Tarasoff* Court was asked when the case started to choose between a duty to warn and a duty to confine; instead, by the case's conclusion, the Court had elected a more ambiguous, more expansive option: a duty to protect, which left practitioners with only vague guidance as to the standard of care in *Tarasoff*-like instances.

Since *Tarasoff*, courts and legislatures have struggled to identify to whom a "duty to warn," a "duty to protect" or any other similar duty is owed. Is there a duty only to clearly identified potential victims? Is there a duty to society-at-large? Courts and legislatures also have struggled to clarify the actions necessary to discharge the duty.

Approximately twenty states have passed statutes granting immunity from liability to providers who properly discharge their duty. Some state laws establish that a duty to warn arises only when a patient has communicated to a practitioner an actual threat of physical violence against a reasonably identifiable victim or victims. Other state laws identify the "victim" as society-at-large, which broadens the practitioner's duty. Regardless of the definition of "victim," state laws say that the duty is discharged and the provider is shielded from liability if the practitioner takes one or more actions including: warning the victim or victims, notifying the police, or seeking civil commitment. Rhode Island has no such laws, however, so the appropriate steps that practitioners should take are unclear.

Most jurisdictions have limited practitioners' liability in *Tarasoff*-like situations. For example, in the case involving John Hinckley, who attempted to assassinate Ronald Reagan and instead injured three bystanders, the Court concluded that the treating psychiatrist owed a duty of care only to persons (not the unidentifiable bystanders) whom Hinckley specifically threatened. Hinckley's psychiatrist, therefore, was not liable for failing to warn the injured bystanders even though the psychiatrist knew that Hinckley owned guns, identified himself as an assassin and collected literature on President Reagan and political assassinations generally. Other jurisdictions have limited the scope of liability by concluding that no duty arises when therapists treat outpatients, reasoning that the outpatient relationship is non-custodial and therefore the provider cannot control the patient's actions.

A minority of jurisdictions have expanded the scope of liability to include unidentifiable victims. In *Lipari v. Sears, Roebuck & Company*, a psychiatric inpatient, upon release from a psychiatric hospital, purchased a shotgun at Sears and fired it into a crowded dining area, killing one individual and seriously wounding another. The Court said that the killer's psychotherapist had a duty to protect nonspecific, endangered third persons, reasoning that the physician-patient relationship imposes affirmative duties on the physician to protect society-at-large.

Rhode Island's Confidentiality Act supports the majority view by permitting the otherwise impermissible disclosure of confidential patient information when a provider believes a specific person

It could be a costly mistake for physicians to conclude that the absence of local judicial interpretation eliminates their duty to potential victims, as there is little question that such a duty exists.



is in danger. As the Rhode Island courts have not decided any *Tarasoff*-like cases, a more expansive ruling concerning the practitioner's duty of care, however, is not out of the question.

A thornier issue for Rhode Island practitioners is how to discharge the duty once it has arisen. In this regard, the ambiguous legacy of *Tarasoff* continues, requiring that the practitioner take "reasonable steps" to protect victims. What is reasonable? In Rhode Island, because of the absence of a specific state statute or relevant case law, the standard of care remains unknown and could include civil commitment, warning the victim, or contacting law enforcement personnel. It would be helpful if the legislature grappled with this issue and decided what actions would be reasonable, so that a practitioner would know what is expected.

Deciding what is reasonable will vary with the treatment setting and practitioner. Rhode Island's civil commitment statute permits involuntary commitment only when a patient is dangerous to himself or others due to a mental disability. As only a psychiatrist or similarly qualified practitioner can make this determination, arguably no other practitioner should be liable for failing to initiate civil commitment proceedings. However, a factfinder might say that in such a situation, the practitioner should consult with a psychiatrist.

Other practitioners faced with a potentially violent patient might want to warn the potential victim or contact the police. If a practitioner warns the victim, the practitioner also should contact the police because, as *Tarasoff* noted, simply warning a victim may prove ineffective. If the practitioner has alerted the police, then arguably the practitioner has placed the matter in appropriate hands and discharged his/her duty.

Tarasoff, its progeny, and related statutes present far-reaching public policy concerns. One concern relates to the protection of confidential patient information. Although the *Tarasoff* Court understood that an effective therapeutic relationship requires that a patient trust his/her therapist, and that such trust includes protection of confidentiality, the Court nonetheless concluded that "the protective privilege ends when the public peril begins."

Practitioners who face *Tarasoff*-like situations may fear that the legal standard will distort their role from caregiver to informant. They may feel increased pressure to involuntarily commit violent individuals because that is the safest course for the practitioner, exposing him/her to the least liability. Yet since there is no therapeutic intervention for individuals who are violent but not mentally ill, commitment to a psychiatric hospital is of no therapeutic benefit to the patient. Societal pressures to detain these individuals leave mental health practitioners feeling more like law enforcers than healers, in part because they will be incarcerating possibly dangerous individuals when police probably do not have adequate grounds to arrest them. One cannot help but wonder whether this changing role corrupts the "special relationship" between physician and patient.

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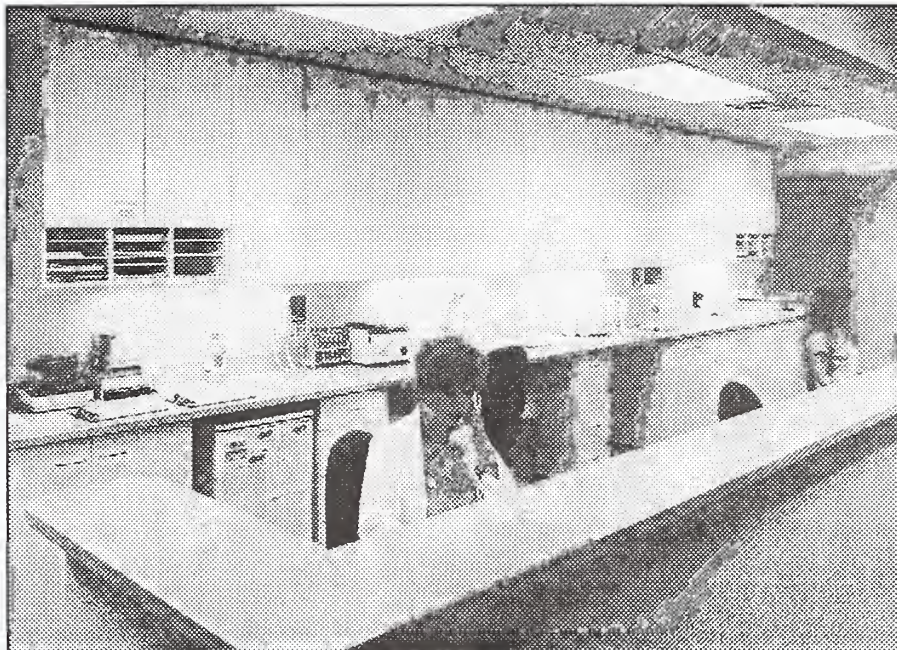
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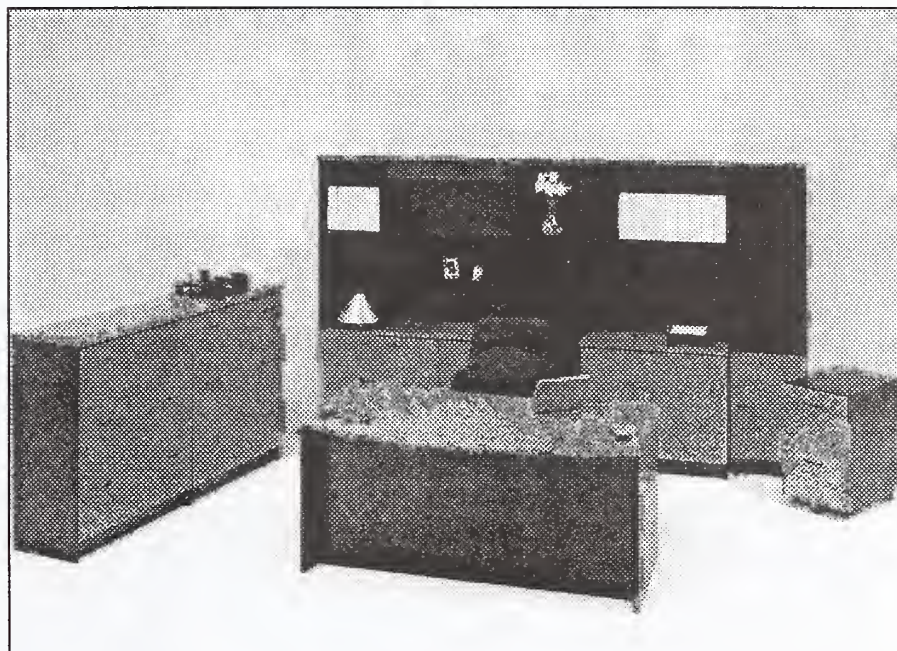
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NINETY YEARS AGO

❧ [NOVEMBER, 1908] ❧

The lead editorial comments on "dangerous occupations as well as many sorts of labor which do not directly imperil the employed but may be more or less prejudicial to health," observing that Germany, through cooperation with its unions and guilds, has achieved significant advances against tuberculosis, lead poisoning and other disorders associated with industry.

A second editorial summarizes the accomplishments of the recently concluded Washington Congress on Tuberculosis, attended by over 400 authorities from Europe and North America. The leading question confronting the participants, as yet unresolved, was whether bovine tuberculosis could be communicated to humans. The majority of the scientists in attendance believed that bovine tuberculo-

sis was readily communicable and hence represented an important source of human disease. Yet another controversial issue was whether tuberculin was effective as a therapeutic agent in the disease. Monetary prizes were awarded to the best exhibits demonstrating medical and social ways of diminishing the spread of tuberculosis.

George S. Mathews, MD, describes a case of pneumococcal arthritis in a 34 year old male laborer who developed acute lobar pneumonia followed in eight days by a pneumococcal arthritis of the left shoulder, bacteremia, then a bacterial endocarditis and death on the 38th day of illness. An autopsy examination confirmed these lesions and, in addition, disclosed a periarticular abscess near the left shoulder. The author also comments on infectious arthritides particularly those associated with gonorrhea, tuberculosis, erysipelas and dysentery.

FIFTY YEARS AGO

❧ [NOVEMBER, 1948] ❧

The etiology, classification and treatment of chronic, non-specific ulcerative colitis are discussed by Anthony Bassler, MD. The author first considers the various theories concerning causation, dwelling on various diplococci held by some to be responsible for the disease. He also mentions the hemolytic *E. coli* sometimes isolated in ulcerative colitis. Mention is made of allergy, vitamin deficiency, biotoxic states, psychosomatic factors as possible primary etiologic agents or secondary contributory factors. There is no definitive treatment, concludes the author, but much can be done to lessen the discomforts, disabilities and complications of the disease. Surgery, he believes, should be undertaken only when medical interventions have failed, when fistulae have appeared, when perforation occurs, when strictures supervene or when hemorrhage accompanies the diarrhea.

Jesse P. Eddy, III, MD, and Palmer Congdon, MD, describe a 79 year old woman with bilateral, non-simultaneous femoral artery occlusions secondary to emboli. In both instances the embolus was removed surgically but the patient expired 37 days later. An autopsy disclosed myocardial infarction with many mural thrombi in both auricles and the left ventricle, probably the origin of the emboli.

An editorial describes the findings of a medical delegation from Rhode Island visiting post-war Germany to inspect the surgical facilities available to civilians and displaced persons.

TWENTY FIVE YEARS AGO

❧ [NOVEMBER, 1973] ❧

Elliot M. Perlman, a graduate student at Brown University [and now a practicing ophthalmologist in the Providence community], William S. Klutz, MD, and Peter Stewart, PhD, describe URINEX, a computerized history-taking system whereby the patient responds to a sequence of nephrological questions and the computer then prints out a concise medical history accompanied by a tentative differential diagnosis. Despite the attractiveness of the system, the authors warn that "the accumulation of such large amounts of data will provide no benefits unless the information can be evaluated easily by the physician who is responsible for patient care. Information must flow freely not only between the patient and the computer, but also between the computer and the physician."

Mitchell Rabkin, MD, discusses the teaching hospital and its role in relationship to the practicing physicians, the patients and the academic community.

Charles L. Hill, MD, summarizes the evolution of the surgicenter and its increasing importance as a more efficient use of limited resources.

An editorial warns of the dangers of eating raw or inadequately steamed clams and cites a recent report in the *JAMA* describing a 21 year old male who developed hepatitis after eating clams harvested from the shores of the Narragansett Bay.



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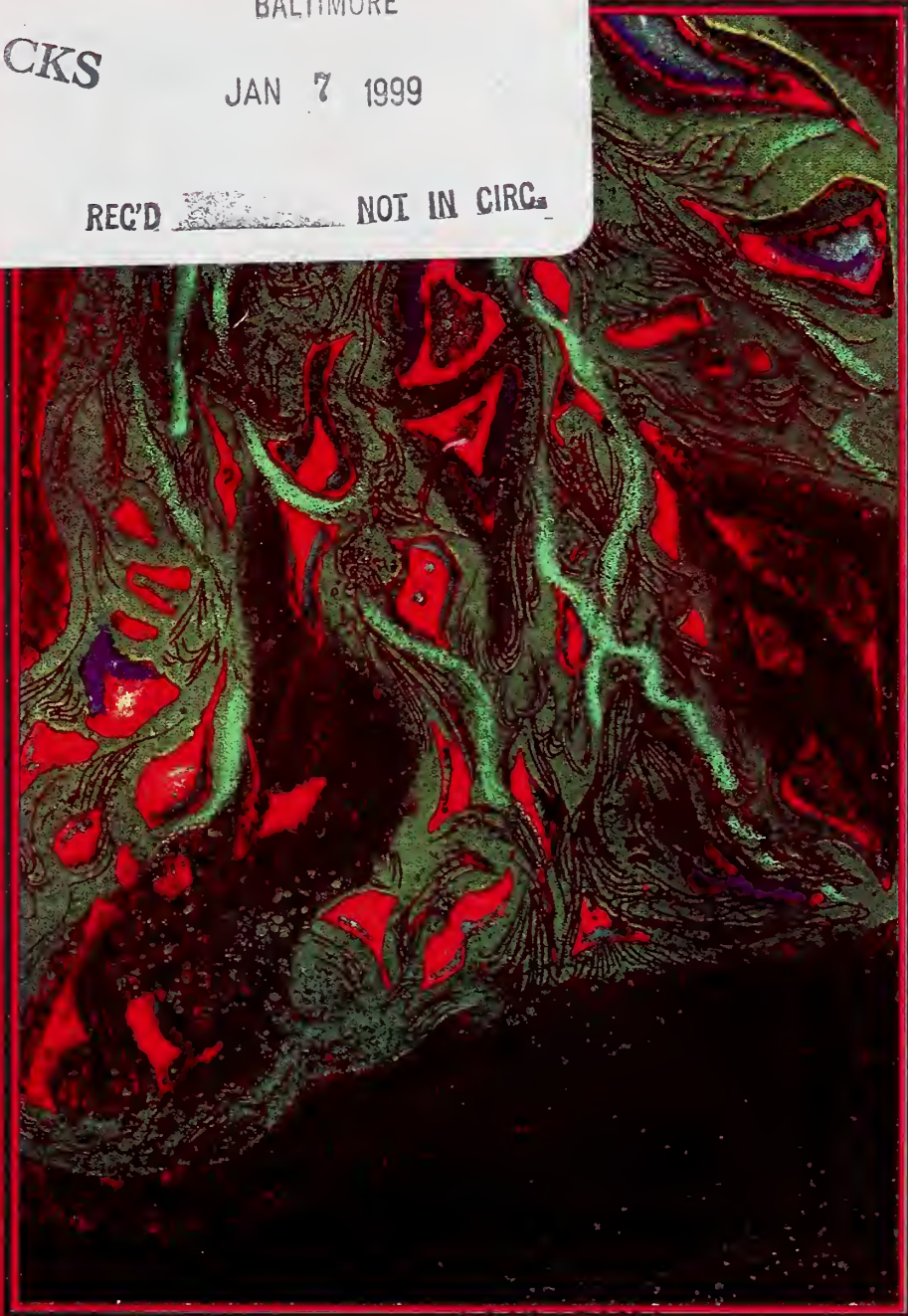
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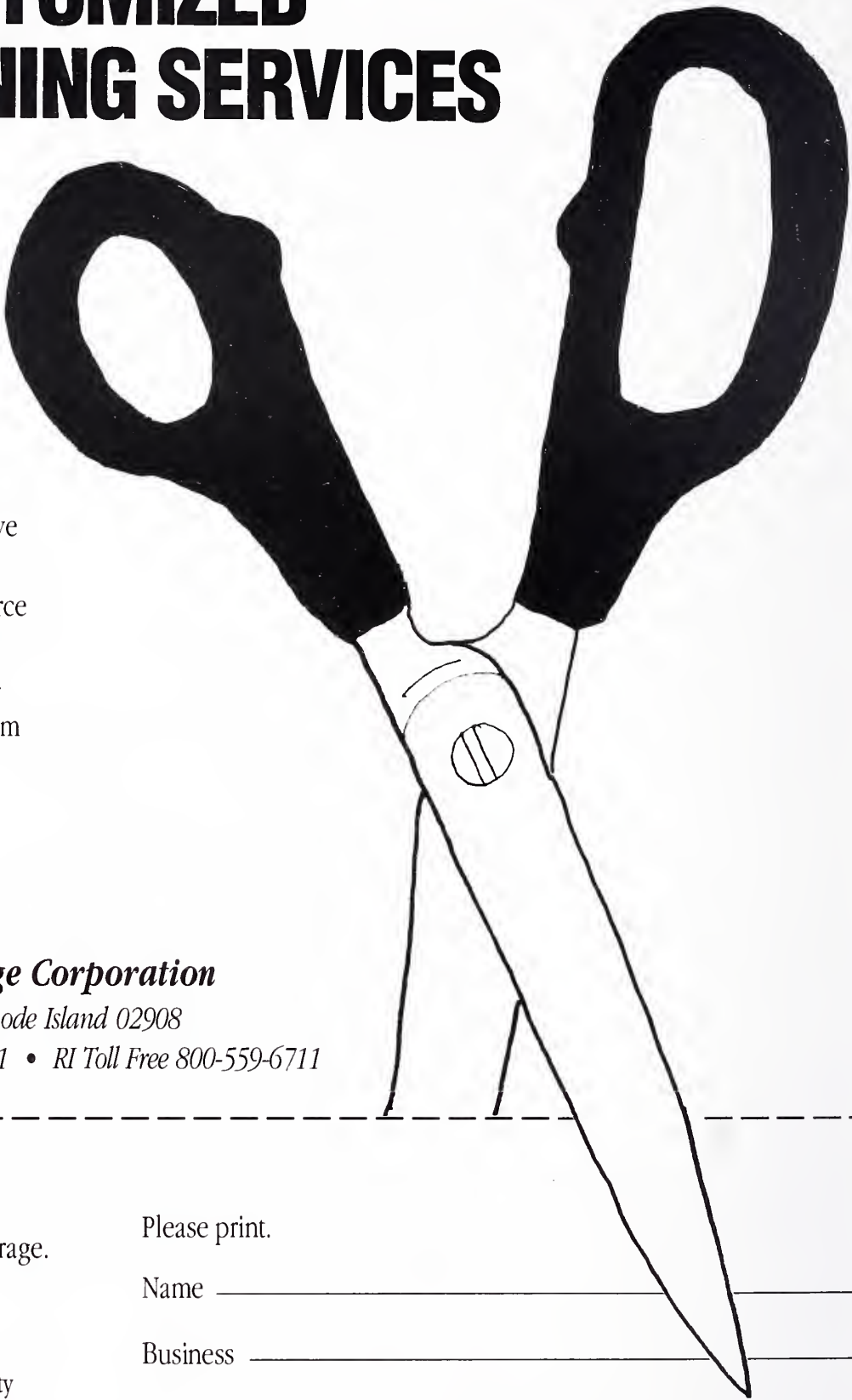
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COMMENTARIES

Transfusion Medicine in the Next Century: Improved Safety in the New Millenium and the Legacy of Ronald A. Yankee, MD

Although we must always look to the future, it is important to reflect on the past and the important achievements of those who have contributed greatly to safe transfusion practice in our community. Ronald A. Yankee, MD, retired on November 9, 1998, as Medical Director of the Rhode Island Blood Center after twenty years of untiring service. Prior to his arrival, the hospitals in Rhode Island were struggling to meet their daily demand for blood products. The need to develop a Community Blood Center was realized, and Ron's organizational skills, technical expertise and charisma were critical in the successful achievement of this goal. Since that time, the Rhode Island Blood Center has gained a respected standing in our community and nationally, largely due to Ron's constant pursuit of excellence and his uncompromising dismissal of mediocre performance. The community owes a great debt to Ron and his contributions will never be forgotten by the Blood Banking community.



Blood products can be considered a family of pharmaceuticals, which, like all pharmaceuticals, have a beneficial effect (potency; efficacy) and the potential for adverse events (safety; purity). Modern transfusion medicine physicians, therefore, practice clinical pharmacology in a restricted area of therapeutics. What separates blood products from other pharmaceuticals is the source (human blood) and the need to engage in compatibility testing. Indeed the logistics of procurement and the nature of tests performed during compatibility testing have largely occupied center stage in transfusion medicine for most of this century.

A new millennium is approaching and with it an increasing awareness that technological advances allow us to take further steps forward to improve the safety of blood products. The public will not tolerate anything less than a total commitment to implement these changes in an expeditious manner. We must not forget the legacy left us by Ron Yankee. Routine removal of allogeneic leukocytes from all blood products will be an early step, likely to be completed before the first year of the new millennium (Sweeney); Better donor screening and new test methodologies will selectively eliminate higher risk donations and technological advances such as



viral attenuation and enzymatic conversion of red blood cells will improve safety (Popovsky, O'Neill, Cannon). Sterilization of blood to achieve microbial attention will occur, eliminating transmissible disease from those residual donations which harbor known, or more importantly as yet unknown, infectious agents (Ben-Hur). As we advance further, substitutes for cellular blood products will likely become available, initially for red cells and later for platelets. These products will be subjected to substantial processing to minimize adverse events (risk). These products will replace the current blood products by the middle of the 21st century (Kim, Greenburg).

As with all pharmaceuticals, a zero risk product is unattainable. As we advance into the decades of the new millennium, however, we will be tantalizing close to achieving this goal.

— Joseph D. Sweeney, MD,
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Nothing to Offer But Blood

The first element of the inner human body cited in *Genesis* was Adam's rib; second was the eye: for when Eve and Adam ate fruit of the tree of knowledge, "Then the eyes of both were opened." And third was blood. When Cain slayed his brother, God says: "Hark, your brother's blood cries out to Me from the ground." Many tissues might have cried out for a reckoning - the heart, the brain - yet to the Hebrews the essence of the soul and the spirit of life rested solely in the blood. Blood was warm, pulsating and when it was shed, life inevitably fled.

Blood is the gift of life and a solemn token of God's generosity. The Bible declares, "For the life of the flesh is in the blood" [*Leviticus* 17:11]. Repeatedly, *Leviticus* condemns any uses of blood except in altar sacrifice. The Lord spoke: "Therefore I say to the Israelite people: no person among you shall partake of blood." Indeed, the dietary laws of the Hebrews decree that blood must be removed before the flesh of a bird or an animal may be consumed.

No culture is without its dual taboos and fascinations with blood. Primitive hunters drank the blood both of vanquished foes and the slain animals of the jungle. Blood of dying gladiators was fought over by spectators in the fervent belief that it would yield renewed strength and vigor. Blood was protective. Moses instructed the beleaguered Israelites to sacrifice a lamb and apply its blood to the lintels and doorposts of their homes, "For when the Lord goes through to smite the Egyptians, He will see the blood... and the Lord will pass over the door." [*Exodus* 12: 23.] A similar ritual was observed in the Moslem custom of slaughtering a camel and smearing its blood upon the lintels of homes to protect against evil spirits.

Blood has been endowed with awesome qualities. It has been called impetuous, noble, even tainted. A passionate person is said to be hot-blooded. Cries for revenge ask typically for blood. [A vengeful lament for lungs or kidneys just lacks the suitable vigor.] Blood seals covenants and binds contracts. Blood is central to the male initiation rites of numerous primitive cultures. Blood has accusatory powers; for when a suspected murderer is brought to the cadaver, only then will the victim's blood flow anew. And Lady Macbeth's rampant conscience was distilled down to a damned, incriminating spot of blood.

If blood truly bestowed such an astonishing range of formidable powers, why then could not human blood be given to a living person for purposes of achieving renewed potency, the curing of disease, or perhaps even immortality? In September of 1492, Pope Innocent VIII lay dying; and in desperation his physicians vainly elected to give him fresh blood taken from three orphan boys. The Pope died; the fate of the three donors is unknown.

Over a century later a prominent British physician, Dr. Richard Lower, successfully transfused blood from one dog to another using an ingenious cannula, designed by Christopher Wren, connecting the two blood streams.

A French physician named Jean-Baptiste Denis then planned a human transfusion. His intentions brought dismay to many who regarded transfusion as a deliberate provocation of Divine authority. Nonetheless, on June 15, 1667, a young nobleman near death was transfused with 8 ounces of fresh sheep's blood. The youth seemed to improve but within days he relapsed and died. Denis attempted further animal to human transfusions with increasingly disastrous results. A courtier in King Louis XIV's entourage was transfused but died suddenly and Denis was then tried for murder. In 1670 the Medical Faculty in Paris banned all further attempts at human transfusion.

A 19th century British obstetrician was appalled by the often mortal blood-loss experienced by many women during delivery. He devised a system whereby blood from the husband was transfused into the veins of the hemorrhaging wife. Five women who might otherwise have died of acute blood loss were thus salvaged by this procedure.

In the next few decades human to human transfusions were occasionally performed with variable results: sometimes with no untoward complications; and sometimes with death to the recipient. Clearly, the procedure was too fraught with hazard to consider it a reasonable form of medical intervention.

Two problems needed to be solved before transfusion might become an acceptable therapy. First, why certain transfusions were safe and others lethal. An Austrian physician transplanted to New York provided the answer. Dr. Karl Landsteiner, in 1900, discovered that there were four major types of human blood and that a successful transfusion required that there be immunologic compatibility between the blood of the donor and the blood of the recipient. The second problem was the observation that blood removed from the body tended to clot quickly; and transfusion of blood containing clots created grave dangers to the person receiving the donated blood. The compelling need for blood transfusion during the early years of World War I stimulated much research and it was found that the introduction of citrates to the extracted blood allowed the specimen to be refrigerated for weeks without clotting or losing its life-sustaining qualities.

Blood transfusion and blood banking have now become an integral part of medicine. Sophisticated laboratories constantly monitor the microbiological purity of each donated specimen as well as ensure compatibility between specimen and designated recipient. About 13 million transfusions are successfully provided each year in this nation. The crude attempts undertaken centuries ago have paved the way for a procedure which has now become remarkably safe, even routine. And blood, once an object of wonder, has been transformed to a life-saving instrument of medicine. Churchill's impassioned call, it must be remembered, offered not heart, not sinew, but blood - along with toil, sweat and tears.

-- Stanley M. Aronson, MD

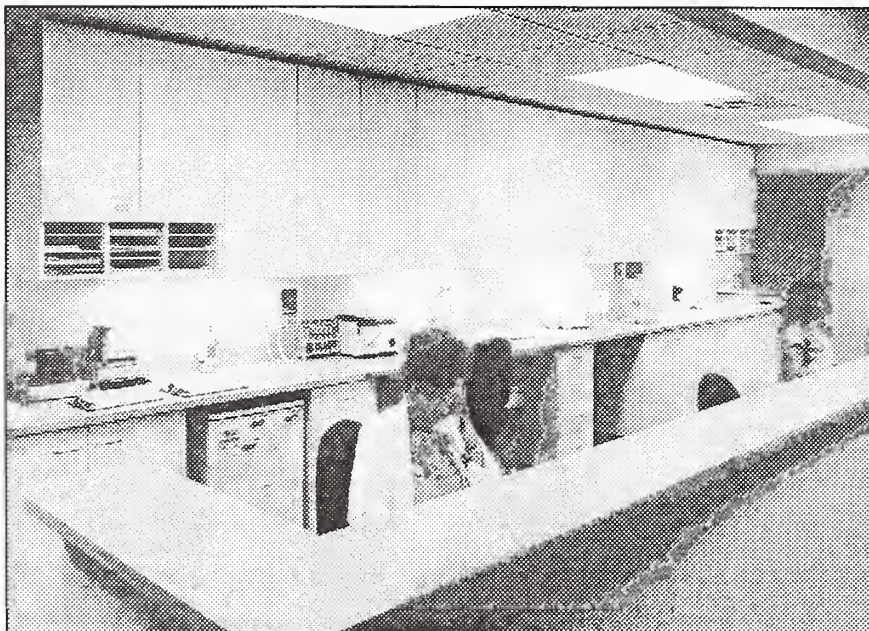
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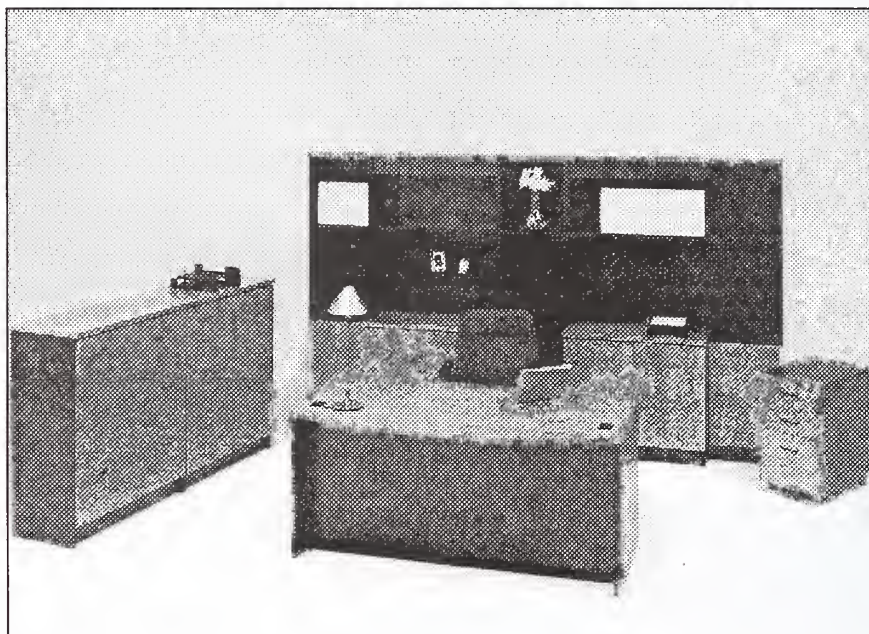
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Health Insurance-Funded Research

Health care has become too expensive for insurers not to invest in clinical research, yet they continue to turn a blind eye to this potentially huge source of savings. It is not possible to calculate how much money health insurers are losing by routinely paying for unproven procedures. These unproven procedures fall into two distinct categories: those that are clearly experimental, such as certain stereotactic neurosurgical procedures and interventional vascular techniques, and those that are generally "accepted" but never "proven" to be effective. While devices and drugs are controlled by the Food and Drug Administration, procedures are not. Drugs and devices require extensive testing to demonstrate both safety and efficacy and insurers may be justified in refusing reimbursement when devices or even medications are used for "off-label" (unapproved) indications although often reversing decisions on appeal. Meeting FDA requirements has become so expensive, however, that all new products, simply to recoup development costs, must be expensive.

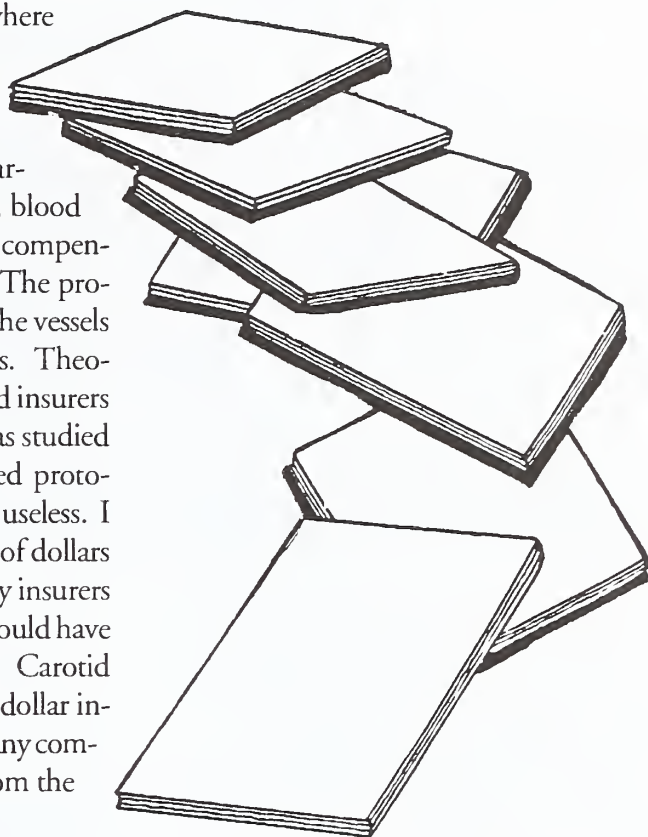
The situation is quite different with procedures that do not require new hardware or medications. A surgeon can decide to do almost anything "within reason" without clearing any review boards or petitioning an insurer in advance. Not along ago a surgeon treated strokes by transplanting abdominal fat pads into the brain. Currently, stenting and angioplasty of carotid arteries is considered an experimental procedure by most neurologists, yet some medical centers offer this procedure and are reimbursed, despite the lack of proof that the technique is effective or even safe. Its efficacy will be valued in an NIH-sponsored protocol that will require tens of millions of dollars while insurers will pay for it at hospitals not in the study.

A case in point of this ass backwards approach is the extracranial-intracranial bypass surgery for carotid occlusion. This seemed like a great procedure for many years. When patients have complete occlusion of a carotid artery, an endarterectomy to open the obstruction cannot be performed, as the upper end of the clot

has propagated into the skull where it cannot be reached. However, the superficial temporal artery on the outside of the skull lies just above the middle cerebral artery. When the two are joined, blood flows into the brain, presumably compensating for the carotid blockage. The procedure had low morbidity and the vessels remained open for long periods. Theoretically it made a lot of sense and insurers paid for it for years. When it was studied prospectively in an NIH-funded protocol, however, it turned out to be useless. I don't know how many millions of dollars were paid, without hesitation, by insurers for this operation. It certainly would have been cheaper to have studied it. Carotid endarterectomies were a billion dollar industry for years before there was any comprehension of who benefited from the procedure.

How many procedures of unproven or dubious efficacy are routinely covered by health insurance? How many expensive operations can be replaced by more effective and cheaper ones? Hundreds of millions of dollars worth. Unfortunately if there is not a patent at the end of the clinical rainbow, a procedure's efficacy will be proven only via the standard route of NIH financing. Getting an NIH grant is slow, cumbersome, and risky. Only a fraction of trials are funded, and even world authorities need to submit grant requests two or three times. This takes hundreds of hours, requires priming money that is scant or non-existent, and chances for funding are never good. In contrast, an insurer can and should say, "This procedure costs us \$200,000,000 a year; and we don't have convincing evidence that it works. Let's invest a fraction of this to find out if it does work. From now on we will only pay for patients who enter the trial." Study centers can be chosen geographically so that patients won't be "deprived."

When the NIH or NSF wants something studied, they send out a request for proposals (RFP). Insurers, individually or in concert, could do the same thing, or convene a panel of experts to review their reimbursements for pro-



cedures and operations that need to be tested. Working hand-in-hand with clinical researchers, insurers can advance medical treatment while reducing costs. Most corporations have research and development budgets. They need to survive. Health insurance sponsorship of clinical research is a sound financial investment that would lower costs. In this time of spiraling costs and constricted access, it is obvious that the time has long passed when one should be sure to get one's money's worth.

Joseph H. Friedman, MD, is Chief, Division of Neurology, Memorial Hospital, and Professor of Clinical Neurosciences, Brown University School of Medicine. He is also Associate Editor-in-Chief of Medicine & Health/Rhode Island.

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Leukoreduction of the Blood Supply in Rhode Island

Joseph D. Sweeney, MD, FACP, FRCPath

There have been substantial changes in transfusion medicine throughout the twentieth century. The early years of the twentieth century saw the important discovery by Karl Landsteiner of the ABO blood group system. This was a critical observation and made possible the practice of blood transfusion without immediate severe reactions. During the early part of the century, the logistics of collecting and storing blood were major challenges, which required solutions. Initially, the question of blood anticoagulation was an important technical problem to be overcome. This was achieved using trisodium citrate (1914-1915). Subsequently, the desire to store red cells became important, particularly to have a supply of blood available for casualties during World War I. High glucose concentrations (dextrose) were introduced during this period. Only later was the anticoagulant acidified in order to prevent the carnalization which occurs when high glucose concentrations are exposed to sterilizing temperatures. The prevention of hemolytic reactions was central in the mind of most transfusion physicians for the first eight decades of this century. The development of procedures which were concerned with preventing hemolytic reactions have become collectively known as "compatibility" testing. This is not to be confused with crossmatching. Crossmatching is only one part of this activity and is becoming increasingly less significant. However, by

1980, concerns for acute hemolytic reactions had largely been overcome, with severe reactions occurring extremely infrequently, probably less than 1:50,000 transfusions.

During the decades from the 1950s to the 1980s, the adequacy of the blood supply to meet community needs became critically important. Pressure was placed on blood suppliers because of the growth of new and effective treatments in cancer therapy and, in addition, a growing increase in the frequency of open heart surgery. By 1980, however, many of these challenges had been met and blood shortages were becoming un-

Abbreviations Used:

AIDS	acquired immunodeficiency syndrome
CMV	cytomegalovirus
EBV	Epstein-Barr virus
ELISA	enzyme-linked immunosorbent acid
FDA	Food and Drug Administration
HHV	human herpes virus
HIV-1	human immunodeficiency virus-type 1
HTLV-1	human T lymphotropic virus, type 1
nvCJD	New Variant Creutzfeldt Jakob Disease
TA-GVHD	transfusion associated graft versus host disease

common.

The period after 1980 presented new challenges. Although the risk of hepatitis transmission had been known

Table 1

Time Period	Issues in Transfusion Medicine	Status
1900-1980	<ul style="list-style-type: none"> • Prevent hemolytic reaction • Develop an adequate blood supply 	<ul style="list-style-type: none"> • Successful: HR < 1:50,000 • Successful: Shortages rare
1970-1996	<ul style="list-style-type: none"> • Prevent Hepatitis transmission • Prevent AIDS transmission • Improve storage conditions • Critically examine transfusion practice 	<ul style="list-style-type: none"> • Successful: Risk is < 1:35,000 • Successful: Risk is < 1:250,000 • Partially successful: new approaches in development • Partially successful: transfusion myths still common
1990-2000	<ul style="list-style-type: none"> • Focus attention on risks of passenger (allogeneic) leukocytes 	<ul style="list-style-type: none"> • Partially successful: methods developed and improved
2000-2020	<ul style="list-style-type: none"> • Blood substitutes • Sterilization of blood 	<ul style="list-style-type: none"> • In development • In development

since the 1940s, serious attempts to prevent hepatitis transmission only developed in the early 1970's, with the exclusion of paid donors and the implementation of hepatitis B surface antigen testing (1972). The important critical observation that Human Immunodeficiency Virus-type 1 (HIV-1) could be transmitted by blood transfusion brought about a very substantial change in both transfusion practices and the public's perception of the blood supply. However, by 1996, with the implementation of donor screening for high risk activity, and anti HIV-1 and p24 antigen testing, the likelihood of AIDS transmission by blood transfusion has become less than 1:250,000. Thus, these important safety issues in transfusion medicine were being reasonably successfully managed by the mid 1990s.

In the last decade, there has been increasing attention paid to the potential for risk reduction in transfusion medicine. First, there is the on-going process to critically examine transfusion practices in hospitals in order to reduce waste and minimize inappropriate transfusion therapy. In addition, there has been increasing work performed to improve the storage conditions of red cells and platelets in order to improve the potency of these products, and, therefore, achieve a better outcome from transfusion. Through-

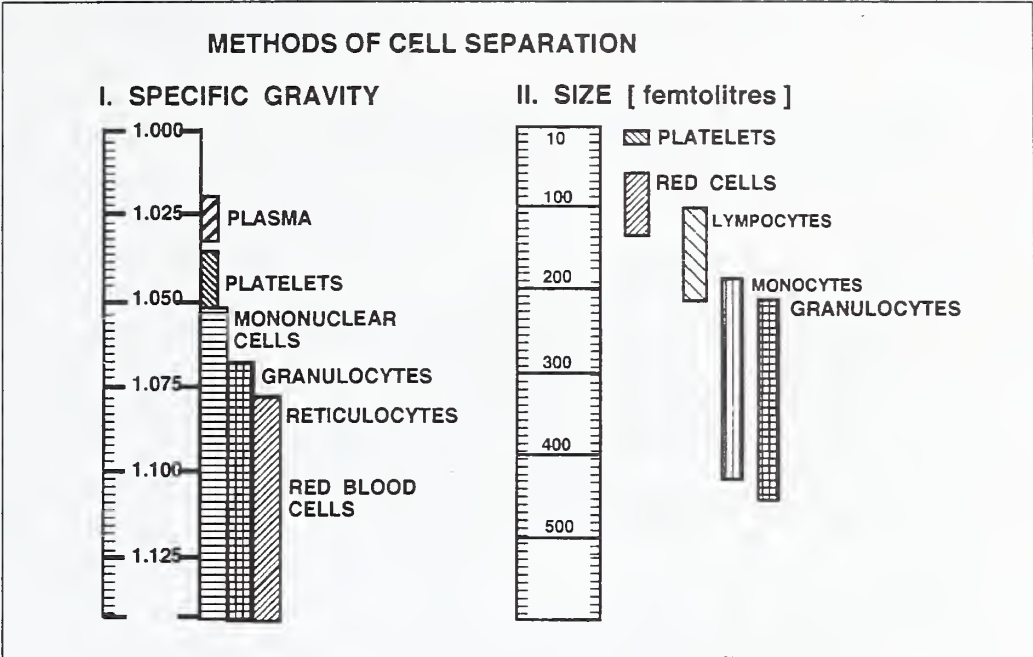


Figure 2: Separation of white cells from the other constituents of blood exploits either differences in specific gravity or size. Note that the overlaps present difficulties in achieving absolute separation.

out this decade, also, there has increasing intention focused on the risks associated with the presence of allogeneic (passenger) leukocytes which are necessarily collected during the blood donation. This latter area is the focus for discussion in this presentation.

As we look into the next century, it is likely that blood substitutes and sterilization programs for blood will dominate technologies for the first two decades. This sketch of events over 120 years is shown in Table 1.

ALLOGENEIC LEUKOCYTES IN BLOOD PRODUCTS

Collecting a unit of blood during a routine donation will result in about two billion (2×10^9) white cells being present in the unit. Since the blood donation will be processed into components, these two billion white cells will be distributed between the red cells, platelets and plasma. The majority (90%) remain with the red cell component: these will be mostly granulocytes. About 8-10% will be present in the platelet concentrates i.e. 200 million or 2×10^8 . These will be mostly mononuclear cells, especially lymphocytes. Less than 2% will be present in the liquid plasma before it is frozen to become fresh frozen plasma. The 2% is, however, approximately 10 million white cells (1×10^7)!! It is clear, therefore, that substantial numbers of white cells are present in each blood component.

Leukoreduction refers to a process in which the white cells are intentionally reduced. This lowers the ratio of white cells to other cells but more importantly, decreases the residual absolute numbers. This can be performed using centrifugation or filtration achieving 99.995% reduction in leukocytes. It needs to be appreciated, however, that the residual 0.005% is actually 5,000 residual leukocytes (Figure 1).

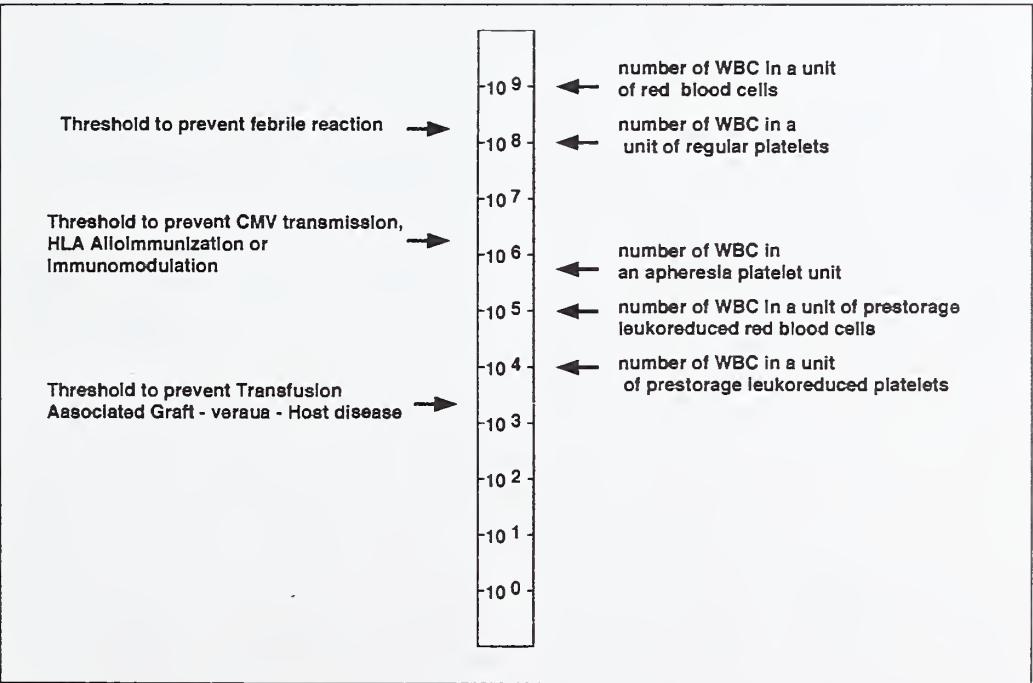


Figure 1: Number of residual leukocytes present in various blood components (right) and the thresholds need to eliminate various adverse events (left). Note the scale is logarithmic to the base 10.

Table 2

Adverse events known or possibly caused by the presence of allogeneic (donor) leukocytes

Known:

1. Non-hemolytic febrile reactions
2. Alloimmunization to HLA antigens
3. Transmission of Leukotropic Viruses: CMV, EBV, HHV-6, HHV-8, HTLV-1
4. Transfusion Associated Graft versus Host Disease
5. Transfusion transmitted toxoplasmosis

Likely:

1. Immunomodulatory effect of blood transfusion resulting in postoperative morbidity
2. Some allergic reactions

Possible:

1. Transmission of new variant Creutzfeldt-Jakob Disease

Table 3

Advantages of Universal Leukoreduction

Known:

1. Reduction in non Hemolytic febrile transfusion reactions for red cells and, if prestorage Leukoreduced, platelets
2. Reduction in HLA alloimmunization
3. Reduction or elimination of transfusion transmitted CMV
4. Improved quality of red blood cells, if prestorage (but not platelets)

Likely:

1. Reduction in allergic reactions
2. Reduction in transfusion-related post-operative morbidity or mortality
3. Reduction or elimination of HTLV-1 transmission by blood transfusion
4. Lack of need to manage a double inventory

Possible:

1. Reduction or elimination of nvCJD

METHODS OF LEUKOREDUCTION

The separation of allogeneic leukocytes from the other cellular constituents of blood is performed currently using one of two methodologies. Firstly, centrifugation can be used, exploiting the difference in density between red cells, platelets and leukocytes (Figure 2). Some apheresis devices use this difference in specific gravity in order to separate

platelets from contaminating mononuclear white cells. Refinements of this technology have recently been developed, such that a greatly leukoreduced platelet product by apheresis is possible.

Filtration however, remains the dominant technology in producing a leukoreduced blood product. Size exclusion technology is partially used to separate leukocytes from other cellular and plasma constituents as leukocytes are larger than the other cells present in blood (Figure 2). However, size exclusion technology alone does not appear to be adequate in producing this desired separation. Various filter surfaces are chemically modified in order to selectively enhance leukocyte removal. This has an important advantage in increasing leukocyte removal, such as separating leukocytes from red cells, but regrettably, also can cause a substantial degree of platelet loss. Thus, currently, separate filter types have to be used to separate allogeneic leukocytes from red cells in red cell products and allogeneic leukocytes from platelets in platelet products. New developments in filtration technology, however, such as whole blood filtration, will likely overcome this problem within the next few years. Under these circumstances, whole blood will be subjected to filtration with removal of allogeneic leukocytes, and the remaining constituents (red cells, platelets and plasma) available for component manufacture.

WHAT ARE THE ADVERSE EVENTS CAUSED BY ALLOGENEIC LEUKOCYTES?

The adverse events associated with allogeneic leukocytes¹ (Table 2) are divided into known, likely and, possible, adverse events. Important among the known adverse events of blood transfusion is the fact that the vast majority of the non-hemolytic, febrile transfusion reactions can be attributed to the presence of allogeneic leukocytes.² These are the common fevers, chills, nausea or vomiting, occasional myalgia, or shortness of breath which are observed in recipients during or immediately after blood transfusion. These reactions tend, in general, to be associated with short-term patient morbidity and rarely, if ever, give rise to a fatal outcome. However, they are extremely uncomfortable and inconvenient for patients, and, as such, are best avoided if at all possible. Patients experiencing severe symptoms may refuse further transfusion, thus, jeopardizing their care. Alloimmunization to Class I HLA antigens has also been documented to be due to the presence of allogeneic leukocytes which express HLA Class II (DR) antigens. Many such cells are present in red cell and platelet products. This is, however, only a significant consideration for patients who are likely to be multiply transfused with platelet products, since refractoriness to platelet transfusions may well develop if alloimmunization to HLA antigens occurs. In practice, this adverse event is the primary reason to use leukoreduced blood in patients receiving chemotherapy for cancer and leukemia who will need multiple platelet transfusions.³ An important adverse event associated with allogeneic leukocytes is the potential to transmit a variety of leukotropic viruses. The most important virus in this group is cyto-

Table 4**Disadvantages of
Leukoreduction**

1. Cost
2. Logistics
3. Decrease in product potency
4. Methodology-related adverse events

galovirus (CMV).⁴ Primary transmission of CMV by blood transfusion is a potentially catastrophic, life threatening event in subpopulations of transfusion recipients, such as newborn infants of low weight (< 2.4 Kg), patients undergoing solid organ or stem cell transplantation or immune deficient (T cell) patients. In addition, the transmission of primary CMV in the first trimester of pregnancy can have devastating teratogenic effects in the fetus. Thus, CMV transmission remains a serious problem for organ transplant recipients and other populations of patients. Intriguingly, a retrovirus, human T lymphotropic virus, type 1 (HTLV-1) is also known to be transmitted by allogeneic leukocytes. Although not quantitatively a major problem from a transfusion perspective in the U.S., this virus has been associated with diseases in recipients, such as T cell leukemias and a form of myelopathy which resembles multiple sclerosis. Allogeneic leukocytes are also the cells responsible for the rare reported cases of transfusion associated graft versus host disease (TA-GVHD). This is a rare adverse event in which the allogeneic leukocytes transfused in the blood product undergo clonal expansion in the host upon stimulation with host antigens, and with resulting host rejection. The importance of this adverse event lies in the mortality rates of at least 90%. It needs to be emphasized, however, that the current methods available for leukoreduction, i.e. filtration and centrifugational based methods do not appear adequate at this time to achieve a residual leukocyte content which will prevent TA-GVHD. Therefore, blood irradiation using gamma photons is the only ac-

cepted approach for prophylaxis at the present time. Other diseases are known to be associated with allogeneic leukocytes such as the transmission of toxoplasmosis, but in practice, this is an uncommon clinical problem and, in itself, does not merit significant attention.

Some allergic reactions are likely to be mediated or caused by allogeneic leukocytes. These allergic reactions are due to the release of substances, such as histamine or interleukin-8 by the allogeneic leukocytes during storage or caused by particulate matter, which may result from disintegrating leukocytes. More importantly, however, is the reported so called immunomodulatory effect of blood transfusion, resulting in postoperative morbidity. Several studies have addressed the issue of patients undergoing surgery who receive both non-leukoreduced blood and leukoreduced blood and the relationship between transfusion and clinical outcome. Recent studies in patients undergoing colorectal surgery shows a very significant difference in outcome for patients who received leukoreduced blood;^{5,6} and a recently reported study from the Netherlands in patients undergoing cardiac surgery shows a reduction in mortality associated with the use of leukoreduced red blood cells.⁷ Insufficient evidence exists at this point to firmly and unequivocally state that these effects can be extrapolated to other clinical situations, for example, the use of leukoreduced blood in urologic, orthopedic, or vascular surgery. However, the data at this time clearly indicates the enormous potential for leukoreduced blood products to attenuate surgical morbidity and, thus, both improve quality of care, patient outcomes and also achieve large cost-savings.

Of great controversy is the question as to whether New Variant Creutzfeldt Jakob Disease (nvCJD) is transmitted by blood transfusion and the role of allogeneic leukocytes, if any, in such transmission. The potential for nvCJD disease to be transmitted by blood transfusion clearly exists, since prion particles may be present in the

plasma of apparently healthy donors who are incubating this disease. The prion particles responsible for nvCJD have been found in lymphoid tissue and trafficking into blood could give rise to infection in transfusion recipients. Intriguing recent experiments have shown an important role for B lymphocytes in presenting prion particles to host lymphoreticular cells in experimental animal models.⁸ For this reason, several European countries have concluded that universal leukoreduction of the blood supply is an important, precautionary step in order to prevent this theoretical possibility. There is less awareness in the United States of this entity, since no cases of nvCJD have been reported. However, this situation requires ongoing vigilance, as the transmission of this condition by blood transfusion would be devastating, particularly in view of recent history where a perception exists that the blood bank community was slow to take steps to effectively prevent HIV transmission by blood transfusion.

**ADVANTAGES OF UNIVERSAL
LEUKOREDUCTION**

The advantages of universal leukoreduction of blood (Table 3) are directly related to a reduction in known adverse events. A reduction in non-hemolytic transfusion reactions, particularly involving platelets, would be an important advantage for those patients who experience transfusion reactions. This would increase the level of comfort and convenience, and improve the quality of care. A reduction in HLA alloimmunization would, in practice, be of value only to those patients who require multiple platelet transfusions and it is routine practice to transfuse leukoreduced products to these recipients at the present time. Elimination of transfusion transmitted CMV disease and other viruses within the Herpes group would be a very important benefit of universal leukoreduction. Blood centers are frequently required to perform serological testing for CMV, for those patients who require low risk CMV products. Elimination of the need for CMV test-

ing would improve efficiency and reduce the cost to the blood center of such serological testing. In addition, there is data to show if the leukocytes are removed prestorage at the point of manufacture, there is an improvement in the quality of the red blood cells during storage. This effect, unfortunately does not exist for platelets, since the leukocytes contaminating platelets tend to be mononuclear cells and not the granulocytes which contaminate red cell products.^{9,10}

There are likely to be other advantages. Elimination of some allergic reactions will clearly improve the quality of care to those susceptible transfusion recipients. Most importantly, a reduction in transfusion related morbidity, such as the postoperative infections or in some circumstances, potentially mortality, would impact on the quality of care for these patient populations. There is also the possibility that HTLV-1 transmission by blood transfusion could be eliminated by leukoreduction. Currently the FDA requires all blood centers to test all blood donations for the presence of anti HTLV-1. Universal leukoreduction could result in the removal of this requirement. This would not only reduce direct cost by eliminating testing but in addition, eliminate the indirect costs of false positives and donor anxiety. Of recent interest is the observation that some strains of HTLV-1 are not detected in the routine ELISA tests for HTLV-1, such that universal leukoreduction could be a better approach to prevent HTLV-1 transmission than serological testing. Also, there is a new concern that other viruses such as EBV or HHV-8 may cause unrecognized morbidity in transfusion recipients. Lastly, it is possible that universal leukoreduction may eliminate or reduce the risk of nvCJD transmission. In practice, this constitutes the basis for the important recent decision by the European countries to pursue universal leukoreduction. An important, perhaps unrealized advantage is that at present, blood transfusion services manage double inventories, since certain types of patients need leukoreduced blood, as indicated

above, and others do not routinely receive such leukoreduced blood. The management of double inventories creates a problem for a modern transfusion service. There would be a substantial improvement in efficiency and associated cost savings with the elimination of the necessity for double inventory management.

*The argument, therefore,
that leukoreduced
blood should be
universally used in
Rhode Island is based
on solid evidence
showing clinical
advantages
associated with such
products ...*



DISADVANTAGES OF LEUKOREDUCTION

Leukoreduction, as with any technology, has potential disadvantages. First and foremost is the added cost. This cost can be captured and quantitated, and for the state of Rhode Island, would be in the order of \$400,000-\$800,000. Although a small number in itself, it needs to be appreciated that this added cost could result in substantial cost savings, if postoperative morbidity due to infections and the cost of dual inventory management were appropriately captured. Thus, although added costs are associated with leukoreduction, in all likelihood, the cost savings associated with a reduction of morbidity related to transfusion would be more than offset, resulting in an economic advantage. The logistics of leukoreduction clearly present challenges to a community blood center. However, if resources are properly applied to the manufacture of these products, this challenge can easily be overcome. It needs to be conceded that the universal application of leukoreduction will result in a decrease in the potency of cellular products, in

the order of 2-8%. It is questionable as to whether this is clinically material and would result in a measurable increase in the need for the total number of units of blood to be transfused. However, it clearly suggests that attention should be paid to the different devices or methods available in order to minimize these losses. Lastly, rare adverse events associated with leukoreduction technology have been described. Activation of the bradykinin system may occur on the surfaces of filters used for leukoreduction¹¹ and, in addition, an unusual syndrome, known as the red eye syndrome¹² or allergic conjunctivitis has been described producing short term morbidity in recipients of prestorage leukoreduced red cells (Table 4).

HAS THE TIME COME TO LEUKOREDUCE THE BLOOD SUPPLY OF RHODE ISLAND?

The above discussion places in context the rationale and the pros and cons for the leukoreduction of blood in Rhode Island. The current major trends and concerns among the European countries, which have gone to universal leukoreduction, are by and large, applicable to the United States. Over the past decade, there has been an increasing understanding of the morbidity associated with allogeneic leukocytes in stored cellular blood products. This has caused subpopulations of transfusion recipients to routinely receive leukoreduced blood. However, a large majority of transfusion recipients are still transfused with regular (non-leukoreduced) blood and quantitation of the causally associated morbidity is uncertain.

Medicine is continually faced with the challenge, however, of making decisions in the face of uncertainty; all knowledge with regard to appropriate decision-making is not always available. As physicians, we continually make decisions regarding individual patient care in the face of uncertainty. These decisions, we hope, are reasonable and prudent for a majority of our patients, represent good practice and result in good outcomes.

Applying the same principles of

making decisions in the face of uncertainty to the community as a whole is logical. Thus, we know that leukoreduced blood products are appropriate for a substantial number of transfusion recipients. We also know that a large number of adverse events are clearly attributable or potentially attributable to the allogeneic leukocytes. We are now becoming aware that potentially devastating illnesses and diseases transmitted by blood transfusion can be reduced or eliminated by the use of leukoreduced blood. Thus, we are already building a strong argument in favor of the routine or universal use of leukoreduced blood. The argument, therefore, that leukoreduced blood should be universally used in Rhode Island is based on solid evidence showing clinical advantages associated with such products, but perhaps more importantly, the exercise of reasonable and prudent judgment in the face of some degree of uncertainty. The above argument focuses on quality of care.

What is unappreciated is that the use of leukoreduced blood may, indeed, turn out to be a cost-minimalization strategy. This is because the adverse events associated with non-leukoreduced blood cause morbidity, and perhaps mortality, with an associated increased cost of care. Thus, if we could capture all the adverse events associated with allogeneic leukocytes and quantitate the economic burden of these events, it is highly likely that the cost savings which result from leuko-reduction will greatly exceed the increased cost incurred with the technology.

Science and medicine continually move forward. Blood as currently transfused is substantially safer than it has ever been in the past. However, for a large number of transfusion recipients, we continue to transfuse a product which contains undesired contaminants. Thus, it behooves us to take the next logical step and remove the contaminating white cells in the blood products transfused. This was also the overwhelming perspective at a recent meeting of the Blood Product Advisory Committee (9/18/98) which reached the same conclusion and for-

mally made such a recommendation to the Food and Drug Administration.

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Decreasing the Risk of Allogenic Blood in the 21st Century

Mark A. Popovsky, MD, E. Mary O'Neill, MD, and Marie Cannon, MD

The blood supply in the United States has never been safer. With the risk of viral infection of less than 1:33,000 per unit transfused, we have achieved a level of safety that only a decade ago may have seemed unreachable. Yet, despite incredible progress, the public remains unconvinced. A recent poll of North Americans found that 80% were "concerned" or "very concerned" about blood safety. Burdened by the perception that blood banks failed to do enough to prevent the entry of HIV entry in the blood supply into the early 1980s, transfusion medicine professionals find that they can never do "enough" to ensure the safety of the blood supply.

Armed with scientific and technological tools, we are in an era in which further gains can be made as we enter the next century. In this article we discuss four areas - donor screening, component preparation, transfusion practice and growth factors - each of which can reduce the risks of allogeneic blood.

CHANGES IN DONOR SCREENING Section 1: Computerized medical history

The vast majority of blood donations are collected from volunteer, unremunerated donors. Once the association was made in the 1960s between paid donors and viral hepatitis in blood recipients, the United States moved toward an all volunteer system. The assumption is that a volunteer donor is more likely to be truthful in response to questions about his/her medical history. The precipitous decrease in post transfusion hepatitis in the 1970s coincides with the movement away from paid donors.

Today's pre-donation medical his-

tory may feel like an inquisition to some, with questions about sexual practices and illicit drug use. Unfortunately, there is evidence that some donors are less than truthful. Studies have shown that 1.9% of donors do not reveal potentially risky behaviors at the time of their blood donation.¹ Obviously, in the absence of blood screening tests capable of detecting every infectious donation, a donor's lack of honesty could have catastrophic consequences for a blood recipient.

Are there better ways to interview prospective blood donors? Work performed in the 1970s revealed that some patients are more comfortable with a computer-based interview than with a physician while answering potentially embarrassing questions. A recent study of blood donors revealed that a computer-based interview was more successful in eliciting a history of HIV-risk behaviors than the standard interview.² In response to concerns about the lack of privacy during the medical health history, blood collection organizations are developing computer programs that will allow the donor to self-administer the interview questions, without the presence of a medical historian. This approach is likely to be in wide use by the year 2000.

Section 2: New tests and technologies

• CHAGAS TESTING

Trypanosoma cruzi, the protozoan parasite responsible for Chagas disease, is endemic in Mexico, Central and South America infecting an estimated 16-18 million people. Infection in these countries is through the bite of

Abbreviations Used:

CMV	cytomegalovirus
EPO	erythropoietin
GAT	genomic amplification technology
G-CSF	granulocyte colony-stimulating factor
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTLV	human T-cell leukemia virus
IPM	infusible platelet membrane
NASBA	nucleic acid sequence-based amplification
PCR	polymerase chain reaction
rHuEPO	recombinant human erythropoietin
SD	solvent/detergent
TMA	transcription-mediated amplification
TPO	thrombopoietin
UV	ultraviolet
WP	window period

the reduvid bug (bedbug) when infected feces from the bug contaminate the bite wound and also through blood transfusion. The infection causes a life long parasitemia during which *T. cruzi* can be detected by antibody assays. The initial infection is asymptomatic in 60% of the patients or may cause fever, lymphadenopathy and hepatosplenomegaly after a 10 - 14 day incubation period. Decades after infection the classic form of Chagas disease can occur with cardiomyopathy, megaesophagus or megacolon. Due to the large migration to the United States of immigrants from these countries, there is a concern about transfusion transmission of *T. cruzi*. Four (4) cases of transfusion-transmitted *T. cruzi* have been documented in the United States and Canada. A recent study,³ conducted in Southern California and Miami blood centers, showed that approximately 1 in 7,000 blood donors

in these areas test positive for Chagas disease. Currently, donors are questioned for a history of Chagas disease which if present results in permanent deferral. However, pending the results of these and other studies, a decision may be made to test donors' blood for Chagas disease.

• VIRUSES

The marked decrease in the risk of transfusion-transmitted viruses has resulted not only from donor screening and selection, but also from the implementation of increasingly sensitive screening tests. Transfusion-transmitted infection results from non-detection of an infection in the "window period" (WP). Continual efforts are being made to shorten the WP.

Genomic amplification technology (GAT)⁴ encompasses many molecular biology technologies including polymerase chain reaction (PCR), ligase chain reaction (LCR), nucleic acid sequence-based amplification (NASBA), and transcription-mediated amplification (TMA). These technologies are based on *in vitro* replication of nucleic acids with a sensitivity for testing many magnitudes greater than current technology. GAT testing of donor blood would have the greatest impact on HCV, reducing the WP from 80 days by approximately forty 40 days. For HIV, GAT testing will result in a shortening of the WP from 16 days by only a few days. Implementation of HCV GAT testing (and probably HIV as well) is expected in the United States in early 1999.

CHANGES IN COMPONENT PREPARATION

Section 1: Viral inactivation

In addition to careful donor selection and testing for infectious agents, methods for virus removal or inactivation have been sought to further improve the safety of blood and plasma products. A number of different physical and/or chemical approaches have been developed or are currently under investigation. These methods have varying applicability, determined by such factors as: virus location (e.g. HBV and HCV in plasma, CMV and

HTLV in leukocytes, and HIV in both plasma and cells) and nature of the component (e.g. cellular vs. plasma, single unit vs. pool).

Techniques for virus inactivation of cellular blood components must be concerned with preservation of cell structure and function. A simple physical method in common use is removal of leukocytes using third-generation filters to produce blood products with reduced risk of CMV transmission. Several photochemical processes that inactivate viruses but do not disrupt cell membranes have also been applied to red blood cells and platelets. The most promising combine irradiation with photosensitive substances that react with viral nucleic acid. An example is psoralens, which are substances found in plants and used with ultraviolet (UV) light in the treatment of psoriasis. The use of psoralens and long wave UV light have been studied as inactivators of hepatitis B and C viruses in platelet concentrates.⁵ The mechanism involves binding of psoralen derivatives to double-stranded nucleic acid. In the presence of UVA light, covalent adducts to pyrimidine bases are formed, which inhibit transcription and replication. A similar technique is under development for virus inactivation of red blood cells using a light-activated dye, dimethyl methylene blue. This molecule binds to nucleic acid, and upon exposure to light, causes breaks in the viral genome. Thus, the infectivity of viruses is destroyed, while red blood cells are left undamaged.

Methods of viral inactivation of plasma have been used in the production of plasma derivatives as well as plasma for transfusion. These methods have evolved more rapidly since it is technically easier to limit damage to plasma proteins as compared to cells. Experimentally, short wave UV light has been used to inactivate non-enveloped viruses in plasma. The technique is improved by the presence of rutin, an antioxidant flavonoid, during irradiation, which markedly reduces the loss of coagulation factor activities. Methylene blue and light have been used in several European countries to

inactivate viruses and can be applied to single units of fresh frozen plasma. This phototreatment is effective against many lipid-enveloped viruses, including HIV, and several non-enveloped viruses. However, it is not effective against hepatitis A virus or intracellular viruses. The latter are eliminated by performing a freeze-thaw step to lyse leukocytes or more recently by filtration of leukocytes. Also, in Europe heat-treated plasma is available for therapy. A 10-hour, 60°C pasteurization process for pooled plasma containing stabilizers has been developed. Other viral inactivation methods under investigation for plasma utilize high energy gamma irradiation, microwave heating, iodine, or ozone.

The solvent/detergent (SD) method of virus inactivation of plasma was licensed by the FDA in 1985 for the manufacture of anti-hemophilic factor concentrate. SD-treated plasma for transfusion was licensed in Germany in 1991 and in the United States in May, 1998. Worldwide, more than 11 million units of SD-treated blood products and 2 million units of SD plasma have been transfused without evidence of viral transmission.⁶ The manufacturing process involves a series of simple steps including a four hour incubation of pooled plasma with an organic solvent and detergent at 30°C. The product is available in standardized doses with consistent levels of coagulation factors and other plasma proteins. Lipid-enveloped viruses, such as HIV and hepatitis B and C, are completely inactivated, while non-enveloped viruses are not destroyed. Hepatitis A and parvovirus B19 are the non-enveloped viruses of concern due to reports of their transmission by transfusion. However, the presence of neutralizing antibodies in the pooled SD product is thought to minimize this risk.

Section 2: Enzymatic conversion of Red Blood Cells (RBC)

Landsteiner's discovery of the A, B and O blood groups nearly a century ago gave rise to modern transfusion therapy. Although the technical capability to identify the correct blood

type of both the patient requiring a transfusion and the blood that will be infused has been widely available for many years, hemolytic transfusion reactions caused by ABO mismatches still occur. Between 1976 and 1985, 37% of transfusion-related deaths were reported due to acute hemolysis. Of these 151 cases, 131 were due to ABO errors.⁷ Many experts believe that due to underreporting, the true incidence may be much higher. Hemolytic transfusion reactions are one of the two most frequent causes of death due to transfusion. These incidents are almost always preventable, caused by breakdowns in the hospital transfusion protocols, either in the laboratory or at the patient's bedside or in the operating room. Deaths are most frequently due to the undetected transfusion of type A or B units to an O recipient. Obviously, if all red cell transfusions were of one type, O, such fatalities would be prevented.

Following the pioneering work of Goldstein et al, a technology has been developed which holds the promise of an all-O blood supply.⁸ Taking advantage of the fact that the distinction between blood groups lies with the terminal sugar that protrudes from the cell membrane, Goldstein and co-workers found that the enzymes (α galactosidase and (α - N- acetyl galactosaminidase, cleave these sugars from group B and A RBC, respectively. The process involves a precise combination of enzyme, temperature and pH. For example each of the approximately 600,000 B antigen sites or 1,000,000 A antigen sites must be cleaved precisely. (An automated device designed to expedite the enzymatic conversion is currently being developed.) Clinical studies of enzymatically converted B-to-O RBC strongly suggest that these cells behave in every way as native O RBC.⁹ While type B RBC represent 10% of the blood supply, 45% are type A; therefore the A-to-O process will be essential to achieve an all O supply.

If the technology becomes commercially available, it could dramatically affect transfusion medicine. First, safety would be enhanced because se-

rious hemolytic transfusion reactions would be virtually eliminated. Waste due to imbalance between the demand and availability of different blood types would also be greatly reduced. Hospitals would most likely be able to significantly reduce their laboratory due to inventory management and decreased compatibility testing (crossmatching). In an all O world, such tests would be perfunctory.

Following the pioneering work of Goldstein et al, a technology has been developed which holds the promise of an all-O blood supply



MODIFYING TRANSFUSION PRACTICES

There is abundant evidence in the medical literature that blood products are often used inappropriately - for the wrong indication or incorrect dose. Although blood is safer today than ever, risks remain. Additionally, there are economic consequences of inappropriate blood utilization. In many hospital laboratories blood products are the single biggest expense. With these issues in mind, how can physicians be motivated to change practices? Studies of transfusion practices reveal that many physicians either over or underestimate the risks of transfusion and lack the fundamental knowledge needed for good transfusion decision-making.

While numerous guidelines for transfusion practice have been developed by expert groups, such documents rarely result in improved practice, in part because many clinicians don't view such guidelines as applying to the patient who needs a transfusion *now*. An approach that is finding greater acceptance and success is educational outreach.¹⁰ A transfusion specialist presents a lecture geared to either medical or surgical specialties emphasizing appropriate indications,

risks and benefits of transfusion. This is followed by a 30-minute visit with the physician who transfuses blood during which educational messages are delivered and specific clinical problems discussed. Results of such educational interventions demonstrate significant and sustained improvement in transfusion practice, with changes of 40% in utilization documented. Studies using this method reveal that this type of intervention is also cost-effective. Hospital administrators and risk managers have shown growing interest in this approach, and it is likely to be more widely adopted over the next decade. The safest transfusion may well become the one that is never administered to the patient.

USE OF GROWTH FACTORS AND OTHER BIOLOGIC MODIFIERS

• Erythropoietin (EPO)

Hematopoietic growth factors¹¹ are naturally produced proteins which regulate hematopoiesis. A number of these have now been produced by recombinant technology and offer an alternative to blood transfusion in certain patients. Recombinant human erythropoietin (rHuEPO) was first approved for use in patients undergoing renal dialysis and resulted in a decrease of red cell transfusions of 500,000 units per year in the United States. Approval for rHuEPO use in the United States now includes HIV patients undergoing zidovudine therapy, cancer patients with anemia, chemotherapy-induced anemia and patients undergoing non-cardiac, non-vascular surgery.

rHuEPO is further being investigated for anemia due to chronic disease including rheumatoid arthritis, anemia in premature infants, sickle cell anemia, bone marrow transplantation, myelodysplastic syndrome and autologous blood donations.

• Thrombopoietin

Thrombopoietin (TPO) is a hematopoietic growth factor that controls the production of platelets. It is a protein produced primarily in the liver and composed of an erythropoietin-like domain and a carbohydrate domain.¹²

Circulating platelets contain high affinity receptors that bind and degrade thrombopoietin. A small concentration of unbound thrombopoietin stimulates platelet production from bone marrow megakaryocytes. *In vitro* effects include stimulation of early and late megakaryocyte precursors as well as erythroid and multipotential progenitor cells

Several clinical trials of recombinant thrombopoietins in humans are underway, and preliminary results suggest a role as a safe and potent stimulator of platelet production without adverse effects. Studies have focused on treating the thrombocytopenia associated with chemotherapy, bone marrow transplantation, and other thrombocytopenic conditions. It has been used to mobilize peripheral blood progenitor cells for collection and has been given to stimulate platelet production in plateletpheresis donors. Other potential uses are in platelet storage and *ex vivo* expansion of platelets.

• Infusible platelet membrane

There have been several efforts to produce a product which could substitute for conventional platelet therapy. One such candidate is infusible platelet membrane (IPM), which is prepared from outdated human platelets.¹³ Platelet membranes are disrupted in a freeze-thaw step, and intracellular components are removed by washing. Heating is used to inactivate any contaminating infectious agents. Following sonication, the membrane microvesicle fraction is lyophilized, giving the product a long shelf life (possibly three years). Studies of IPM have shown a reduction in prolonged bleeding times in thrombocytopenic rabbits. Phase II clinical trials in humans are evaluating the efficacy of IPM as treatment for acute bleeding in refractory thrombocytopenic patients.

• Granulocyte colony-stimulating factor (G-CSF)

G-CSF is a hematopoietic growth factor produced by monocytes, fibroblasts, and endothelial cells. It primarily regulates the function of neutrophils within the bone marrow

and affects neutrophil progenitor proliferation and differentiation. It has minimal effects on other cell lineages. Currently, recombinant G-CSF is used to reduce the duration of neutropenia and incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy or bone marrow transplantation. There is extensive experience with its use for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis for autologous and allogeneic transplantation. In addition, there has recently been a renewed interest in granulocyte transfusion therapy for neutropenic patients with bacterial or fungal infections unresponsive to antimicrobial therapy. Collection of neutrophils requires donor stimulation so that an adequate dose can be obtained by granulocytapheresis. Studies have found that yields are significantly increased when a combination of G-CSF and steroids are administered to donors. Adverse effects associated with the use of G-CSF include bone pain, headache, fatigue, and insomnia. Symptoms are generally mild and well tolerated.

CONCLUSION

Many of this century's greatest medical advances have been enabled by transfusion therapy. For the last 50 years, much of the effort in transfusion medicine has been devoted to either increasing the availability of blood products or creating more specialized products. With greater insight into the risks of allogeneic transfusion, we enter the new century with knowledge as to how to use less blood with greater precision. The blood that will be transfused will have an unparalleled level of safety.

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Inactivation of Pathogens in Blood and Blood Products

Ehud Ben-Hur, PhD

The emergence of HIV as a transfusion-transmitted virus in the early 1980s and the concern it raised about the safety of the blood supply has stimulated a massive effort to reduce the risk of transfusion-transmitted pathogens. This effort has been expressed in the introduction of the following approaches:

1) the use of questionnaires for deferral of high-risk donors.

2) the implementation of serological tests for the major viral pathogens HIV, HBV and HCV as well as HTLV.

3) the introduction of virus inactivation methods in blood products. Due to these efforts the risk of transfusion-transmitted pathogens is essentially nil for blood products and FFP. However, for the cellular blood components, RBCC and platelet concentrates, there is still a very low risk remaining,¹ primarily due to the window period (the time between infection and appearance of detectable antibodies).

Efforts are underway to eliminate the remaining risk in RBCC and platelet concentrates. These efforts are a two-pronged approach: pathogen detection based on nucleic acid amplification technologies, such as PCR, and pathogen inactivation. There are a

number of advantages for adopting pathogen inactivation procedures, in addition to eliminating the risk of pathogen transmission. The window period will no longer be of concern and efforts to reduce it by direct detection of pathogen nucleic acid will no longer be needed. Error in testing or the inadvertent release of blood that tests positive will not result in pathogen transmission. Pathogens that are not tested for, including new ones, will be eliminated, obviating the need to introduce new tests.

PATHOGEN INACTIVATION IN BLOOD PRODUCTS

A. Wet heat (pasteurization)

The use of heat (60°C, 10 h) in the liquid state is the oldest method of sterilization and is named after its inventor, L. Pasteur. Because most proteins are heat-labile, they have to be stabilized in the blood product to be treated by the addition of sugars, amino acids and salts.² These additives prevent protein denaturation and loss of biological activity of the blood product. The pathogenic viruses are stabilized by the added solutes to a much lower extent than that of the clotting factors. Treatment that achieves a sufficiently high level of virus inactivation (over 6 log₁₀) results in 60-80% re-

Abbreviations Used:

FFP	fresh frozen plasma
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus
MB	methylene blue
PCR	polymerase chain reaction
PUVA	psoralen-plus-UVA light
RBCC	red blood cell concentrates
ROS	reactive oxygen species
SD	solvent detergent
TNBP	tri(n-butyl) phosphate

covery of clotting factors. This is an easily implemented process but non-enveloped viruses are killed to a lesser extent than lipid-enveloped viruses (such as HIV, HBV and HCV).

B. Dry heat

Pathogen inactivation by heating of lyophilized blood proteins occurs at higher temperatures and takes a longer time compared to pasteurization (due to protein stabilization in the absence of water). To achieve HIV elimination from lyophilized factor VIII heating has to be at 80°C for 72 h.³ Recovery

Table 1. Safety of virally sterilized coagulation factor concentrates*

Method	Quantity tested (U x 106)	No. of patients infected / No. treated		
		HBV	HCV	HIV
Wet heat (60°C, 10 h)	18.8	2/?	2/95	0/237
Dry heat (80°C, 72 h)	0.1	0/16	0/32	0/32
Dry heat and vapor (60°C, 10 h)	1.1	4/46	0/70	0/110
Solvent-detergent	17.6	0/55	0/449	0/524

* The results are from hemophiliacs who received standard therapy with coagulation factor concentrates virally sterilized by the indicated method. Following infusion, patients were monitored for 6-12 months using standard serologic assays. Data are from Ref. 9.

of factor VIII activity exceeds 90%. The advantage of dry heating is that it can be performed in the final container, eliminating the possibility of post-treatment recontamination.

C. Solvent Detergent

The use of the solvent tri(*n*-butyl) phosphate (TNBP) with Tween 80 or other detergents, disrupts the viral lipid envelope with a concomitant inactivation of lipid-enveloped viruses.⁴ The treatment is rapid (4 h at 24-30°C), plasma proteins are not affected and recovery of clotting factors can reach 100%. The added solvent and detergent are removed after treatment with hydrophobic chromatography using a C18 resin. The safety of solvent detergent (SD)-treated blood

products with respect to transmission of HBV, HCV and HIV is supported by 14 clinical trials (Table 1). In addition, SD-treated blood products are used in the clinic since the mid-1980's with an excellent viral safety record. Advantages of SD-treatment include its ease of implementation in a factory setting, and its very high level of virucidal action under conditions where virtually all proteins are unaffected.

PATHOGEN INACTIVATION IN BLOOD COMPONENTS

A. Fresh frozen plasma

The excellent safety record of coagulation factors treated with SD encouraged the development of SD-treated plasma.⁵ The procedure involves pooling of 2500 units of FFP,

treatment with 1% TNBP and 1% Triton X-100 at 30°C for 4 h, and removal of the reagents by hydrophobic chromatography. The final product is sterile-filtered and frozen. HAV (which is rarely transmitted by blood transfusion) and parvovirus B19 (pathogenic only in immune-compromised patients), both non-enveloped viruses, are not killed by SD treatment. However, due to pooling, SD-treated plasma has anti-HAV and anti-parvovirus antibodies in quantities at least as high as in immune globulin preparations used to treat parvovirus infections and to prevent HAV spread. The coagulation factor content is similar to that of the start pool and is more consistent than that found in individual donor units. Toxicological studies indicate that the tiny

Table 2. Comparison of the approaches for virus inactivation in blood

Table 2. Comparison of the approaches for virus inactivation in blood			
APPROACH	BLOOD COMPONENT	ADVANTAGES	DISADVANTAGES
Wet Heat	Purified proteins	Convenient - all viruses are susceptible.	Protein activity recovery is medium
	Plasma		Non-enveloped viruses killed to a lesser extent Plasma must be pooled
Dry Heat	Purified proteins	Can be performed in the final container High protein recovery.	Non-enveloped viruses are not completely killed.
Solvent-detergent	Purified proteins	Enveloped viruses very sensitive.	Non-enveloped viruses are not inactivated
	Plasma	Recovery of protein activity is close to 100%	Plasma must be pooled.
UVC light	Purified proteins	Inactivates all virus types.	Rutin must be added to protect protein activity.
	Plasma		Specialized equipment required.
Photosensitization	Plasma	The only way to sterilize cellular components.	Not yet commercially available, except for methylene blue for plasma in Germany and Switzerland. Viral safety yet to be proven.
	Platelets	Plasma does not have to be pooled.	
	Red cells		
Chemical inactivation (S-303, imines)	Red cells	Convenient	Not yet commercially available
		All pathogens are susceptible	Potentially mutagenic if not completely neutralized.

amounts of solvent and detergent that remain (below 3 ppm) are safe.

SD-treated plasma has been approved for use in Europe and the United States. No virus transmission has occurred in the 3 million units of SD-treated plasma infused so far.

Methylene blue and visible light.

Methylene blue (MB) is a photosensitizer, i.e. in conjunction with light it can inactivate biological systems. Because the presence of oxygen is required for the photochemical reaction, MB is a photodynamic agent. The virucidal action of MB is well known but the mechanism of action is not entirely clear. Nucleic acid damage is usually produced as a result of MB and photosensitization and could be the main lesion responsible for inactivation.

In Germany and Switzerland individual FFP units are treated with 1 μ M MB and white fluorescent light for 1 h.⁶ The individual units are refrozen and stored for later use. While many viruses as well as bacteria can be inactivated by this process, complete virus studies, including hepatitis viruses and a demonstration that an infectious unit can be rendered non-infectious, have yet to be reported. The advantage of this approach compared to SD-treatment is the lack of pooling (i.e. recipients would receive plasma from individual donations rather than from a plasma pool). On the other hand, treatment of individual units does not allow for careful monitoring and control procedures that can be achieved with plasma pools processed in a factory.

MB photodynamic treatment of plasma resulted in no adverse reaction in recipients but there is one case of HCV following transfusion of 1.7 million units, although its source has not been established. The *in vitro* coagulation capacity of MB-treated plasma is reduced, mainly because of reduced fibrinogen and factor VIII activity. Considerable investigation is still required prior to the clinical use of MB-treated plasma in the USA.

B. Platelet concentrates

The cellular components of blood

are more difficult to sterilize than protein solutions because cell structure and function are disrupted more easily. The challenge is eased somewhat because red cells and platelets lack a nucleus and are non-replicating. A decontamination process must leave platelet function intact during the five days' storage period and they should circulate normally after transfusion.

The inactivation of viruses in blood proteins and plasma has made the transfusion of these products absolutely safe with respect to transmission of HBV, HCV and HIV.



The use of psoralens and UVA light (PUVA) is a promising approach for inactivation of pathogenic organisms in platelet concentrates. A psoralen derivative termed S-59 is now in Phase II clinical trials in the USA.⁷ Psoralens preferentially bind to nucleic acids in the dark and upon exposure to UVA light form adducts with pyrimidines, which effectively inhibit nucleic acid replication and function. As a result, PUVA inactivates not only pathogens but also leukocytes. The inactivation of the latter is beneficial since transfused leukocytes may lead to alloimmunization, non-hemolytic febrile transfusion reactions and graft-versus-host disease.

In addition to covalent binding to nucleic acids upon exposure to UVA light, psoralens can also produce reactive oxygen species (ROS) and induce photodamage in lipids and proteins. To circumvent that potential problem, the plant flavonoid rutin has been added as a quencher of ROS to eliminate damage to platelets during treatment with the psoralen AMT and UVA light.⁸

An added advantage of PUVA is its ability to inactivate not only viruses

but also blood-borne parasites and bacteria in platelet concentrates. Because the risk of bacterial contamination is currently the reason for limiting the storage of platelet concentrates to 5 days, inactivation of bacteria may extend the allowable storage time to 7 days.

C. Red Blood Cell Concentrates

PUVA cannot be used for the sterilization of RBCC because of the strong absorption of UVA light by hemoglobin. Only red light (> 600 nm) can effectively penetrate RBCC and for this reason sensitizers that absorb maximally in the red are being studied. These compounds, e.g. dimethyl methylene blue and the silicon phthalocyanine Pc 4 are photodynamic agents. Because of the production of ROS, quenchers have been added in conjunction with Pc 4 to preserve RBC.⁹ Another approach has been to use chemicals that react with nucleic acid in the dark. A psoralen derivative termed S-303 was reported to inactivate a variety of viruses and bacteria in RBCC at a concentration of 150 μ g/ml without affecting RBC parameters *in vitro* and *in vivo*.¹⁰ This compound is now in Phase I clinical trials. Another class of compounds that can inactivate viruses in the dark are imines, which alkylate nucleic acids.¹¹ Their compatibility with RBC has yet to be reported.

CONCLUSIONS

The inactivation of viruses in blood proteins and plasma has made the transfusion of these products absolutely safe with respect to transmission of HBV, HCV and HIV. The addition of nanofiltration or UVC irradiation to the currently established methods (heat and SD-treatment) should make these products safe also with respect to HAV and parvovirus B19, the two non-enveloped viruses that can be transmitted by plasma derivatives. The remaining challenge is the sterilization of RBCC and platelet concentrates. PUVA and S-303 are in clinical trials and other approaches will likely enter clinical trials soon. Table 2 summarizes the relative merits of these methods. Since none of them is per-

fect, current screening methods are unlikely to be discontinued. On the other hand, adoption of virus inactivation procedures may make the addition of new screening tests unnecessary.

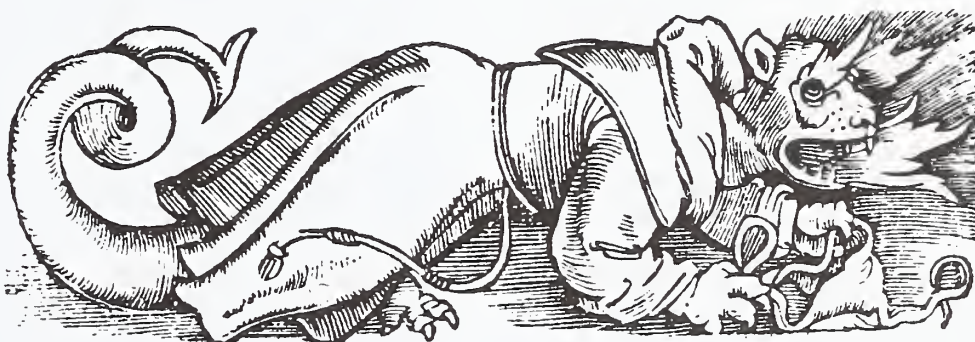
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Substitutes for Red Cell Transfusion: 2000-2015 A.D.

Hae Won Kim, PhD, and A. Gerson Greenburg, MD, PhD

There is a complex relationship between oxygen delivery, vascular volume, cardiopulmonary physiology and mammalian survival. Without continued blood perfusion of vital organs, life cannot be sustained. Moreover, circulation can be continued only when there is an adequate intravascular volume. Blood carries and delivers oxygen to tissues based on the amount of hemoglobin, an essential element for survival. If a significant amount of blood is lost (e.g., after a traumatic injury or during a surgical procedure) circulation generally and perfusion of vital organs specifically becomes inadequate; the decreased oxygen carrying capacity impairs oxygen delivery and normal function is impaired. Intravascular blood volume can be replaced with many fluids such as crystalloids and colloids. However, the only currently available treatment for a decreased oxygen carrying capacity is red blood cell transfusion.

Since Landsteiner's discovery of ABO blood types in 1901, blood transfusion has evolved as a lifesaving treatment for many hemorrhagic conditions. Red cell transfusion restores the intravascular volume and provides additional oxygen carrying capacity allowing adequate tissue perfusion and oxygenation. Although blood transfusion has saved innumerable lives, it is not without risks. Allogeneic blood transfusion can cause fatal hemolytic reactions, transmit blood borne infectious agents, or compromise immune function. Since the early 1980s when AIDS was first identified, there has been a general tendency to avoid allogeneic blood transfusion for fear of infectious disease transmission.

At the same time, there has been a notable increase in creating options and development of alternatives to allogeneic blood transfusion. These

changes in transfusion practice together with technological advances in screening donated blood have markedly reduced the incidence of transfusion-related infections. Today's blood transfusion is safer than ever: risks of transmission for human immunodeficiency virus and hepatitis B virus are 1 in 493,000 and 1 in 63,000, respectively.¹ And yet, the associated risks should not be understated. The clinical benefits of red cell use must be carefully weighed against potential risks and the risk of deciding to not transfuse.

CURRENT ALTERNATIVES TO ALLOGENEIC BLOOD TRANSFUSION

Blood transfusion can be avoided by minimizing blood loss during a surgical procedure through modified surgical techniques and prudent use of available hemostatic and anti-hemorrhagic agents. In addition, in many cases shed red cells can be salvaged and reinfused after washing and filtration. New and improved techniques and new technologies continue to evolve to minimize blood loss and enhance salvage of lost blood.

Despite careful surgical techniques and blood conservation/salvage measures, blood transfusion often becomes necessary. In this case, exposure to allogeneic blood can be reduced or

Abbreviations Used:

CK	creatine kinase
DBBF	bis(3,5-dibromo salicyl)-fumarate (diaspirin)
DCL	diaspirin cross linked
DPG	2,3-diphospho glycerate
FBOC	perfluorocarbon-based oxygen carrier
FiO ₂	fraction of oxygen in inspired gas
Hb	hemoglobin
HBOC	hemoglobin-based oxygen carrier
kD	kilo dalton
LDH	lactate dehydrogenase
LEH	liposome encapsulated hemoglobin
NFPLP	2-nor-2-formyl PLP
NO	nitric oxide
ODC	oxygen delivery capacity
P ₅₀	oxygen tension at which 50% of Hb oxygen binding sites become saturated with oxygen
PaO ₂	arterial oxygen tension
PCO ₂	carbon dioxide tension
PEG	polyethylene glycol
PFOB	perfluoro octyl bromide
PLP	pyridoxal-5'-phosphate
PO ₂	oxygen tension
PvO ₂	venous oxygen tension
RCS	red cell substitute
SFH	stroma-free hemoglobin
t _{1/2}	intravascular circulation half-time
w/v	weight of solute per unit volume solvent (e.g., g/ml)

avoided altogether through an autologous transfusion procedure. If the surgery is elective and transfusion is likely to be needed, an appropriate amount of blood can be withdrawn before the scheduled procedure and stored for use during operation. Typically, 1-4 units of red cells are taken; if combined with intra-operative hemodilution, 6-7 units of blood may be made available for a given patient, enough for most elective surgical procedures.² Due to fear of infectious disease transmission, this procedure has become increasingly popular. However, autologous transfusion is limited to elective surgical cases

and applicable only to those patients who can safely donate the necessary amount of blood without adverse health consequences. Patients with significantly compromised cardiopulmonary and renal functions are not generally eligible. Further, fatal transfusion reactions due to clerical errors still can occur with this procedure and the risk of immune suppression is not known.

RED CELL SUBSTITUTES: NEW ALTERNATIVES ON THE HORIZON

Increased use of the currently available alternatives to allogeneic blood transfusion, such as autotransfusion or hemodilution, coupled with more rational transfusion practices could further reduce the need for bank blood in subsets of patients who had required red cell transfusion for additional oxygen capacity. In an emergency or if a patient can not donate his/her own blood, these methods are not an option. An oxygen-carrying fluid that is readily available, free of infectious agents, and can be used regardless of the recipients erythrocyte antibody status would be highly desirable. Studies of red cell substitutes (RCSs) have been ongoing for decades but only recently have a few candidates reached active clinical testing. Two distinct approaches, hemoglobin-based oxygen carriers (HBOC) and perfluorocarbon-based oxygen carriers (FBOC), are the most promising to date. If no major toxicities are revealed in clinical trials, one or more of the candidate RCSs from these groups may become available clinically. The time frame is less certain for the regulatory process and the testing are complex issues.

PERFLUOROCARBON-BASED OXYGEN CARRIERS (FBOC)

Perfluorinated carbons have a unique property of dissolving large amounts of gases. The amount of dissolved oxygen or other gases in perfluorocarbons is proportional to ambient gas tension according to Henry's Law. Under normal ambient condition, some pure perfluorocarbons dissolve more than 50ml of oxygen per

100ml. In pure perfluorocarbon liquid saturated with oxygen, a mouse could sustain life if completely submerged in the liquid.³ Although perfluorocarbons dissolve sufficient amounts of oxygen to sustain life, these are oil-like fluids that do not mix with water. To be useful as a oxygen carrying red cell substitutes, perfluorocarbons must first be emulsified in buffered physiological electrolyte solution. The first perfluorocarbon emulsion in clinical trials was Fluosol-DA, a 20% (w/v) co-emulsion of perfluorodecalin and perfluorotripropylamine with egg yolk phospholipid and Pluronic-68[®] as emulsifying agents. Breathing ambient air and with the normal arterial and venous oxygen tensions, Fluosol-DA could deliver only 0.4ml oxygen per 100ml. To meet the metabolic oxygen demand, patients had to breathe pure oxygen ($FiO_2=1.0$). Not generally acceptable, this material failed to show efficacy in clinical trials due to low oxygen delivery capacity under ambient conditions. Further, Pluronic-68[®] used as an emulsifying agent was responsible for occasional complement activation. Recently, a 60%(w/v) emulsion of perfluorooctyl bromide has been developed using egg yolk phospholipid as a sole emulsifying agent.⁴ Under normal arterial and venous oxygen tensions (100 and 40 mmHg, respectively), this FBOC can unload as much as 1.3ml oxygen per 100ml (Figure-1). Although this is a remarkable improvement in oxygen delivery capacity, it still falls far short of normal oxygen delivery capacity of blood (5ml O_2 /100ml blood at 15g Hb/dl). It may not deliver sufficient oxygen for normal organ function. To ensure sufficient oxygen delivery, patients must still breathe 100% oxygen, a situation avoided whenever possible because of adverse effects on the lungs.

HEMOGLOBIN-BASED OXYGEN CARRIERS (HBOC)

Hemoglobin (Hb) is a 64kD tetrameric ($\alpha_2\beta_2$) intraerythrocytic protein that reversibly binds oxygen and carbon dioxide. Each α or β subunit contains one ferrous heme group which binds one oxygen molecule; when fully saturated with oxygen in the lungs one Hb molecule can carry four oxygen molecules. At tissues, where oxygen is consumed for metabolic reactions, local factors (e.g., pH, temperature, P_{CO_2}) cause Hb to undergo conformational change from high oxygen affinity state (R-state) to low oxygen affinity state (T-state). In addition, 2,3-diphosphoglycerate (DPG), an allosteric effector present in the red cells, binds to Hb further decreasing the oxygen affinity of Hb. The DPG binding to Hb greatly facilitates oxygen offloading. While oxygen is being unloaded at tissues, CO_2 binds to the primary amino groups of globin chains. The resulting carbamino-Hb is then transported to the lungs (CO_2 transported in this way amounts to over 20% of the total CO_2 transported in the blood). The local conditions in the lungs (e.g., higher PO_2 , higher pH, lower temperature) cause Hb to shift back to the high oxygen affinity state (R-state) and dissociate DPG. The R-state favors Hb to release CO_2 while recombining with O_2 . The released CO_2 is then exhaled.

STROMA-FREE HEMOGLOBIN (SFH)

Because Hb uniquely binds oxygen and carbon dioxide reversibly, the idea of using purified Hb as a substi-

Table 1. Key Approaches in Red Cell Substitute Development

Hemoglobin based oxygen carriers (HBOC)

Stabilized Hbs
Polymerized Hbs
Conjugated Hbs
Encapsulated/Embedded Hbs
Recombinant/Transgenic human Hbs

Perfluorocarbon based oxygen carriers (FBOC)

Perfluorooctyl bromide emulsion
Perfluorodichloro octyl bromide emulsion

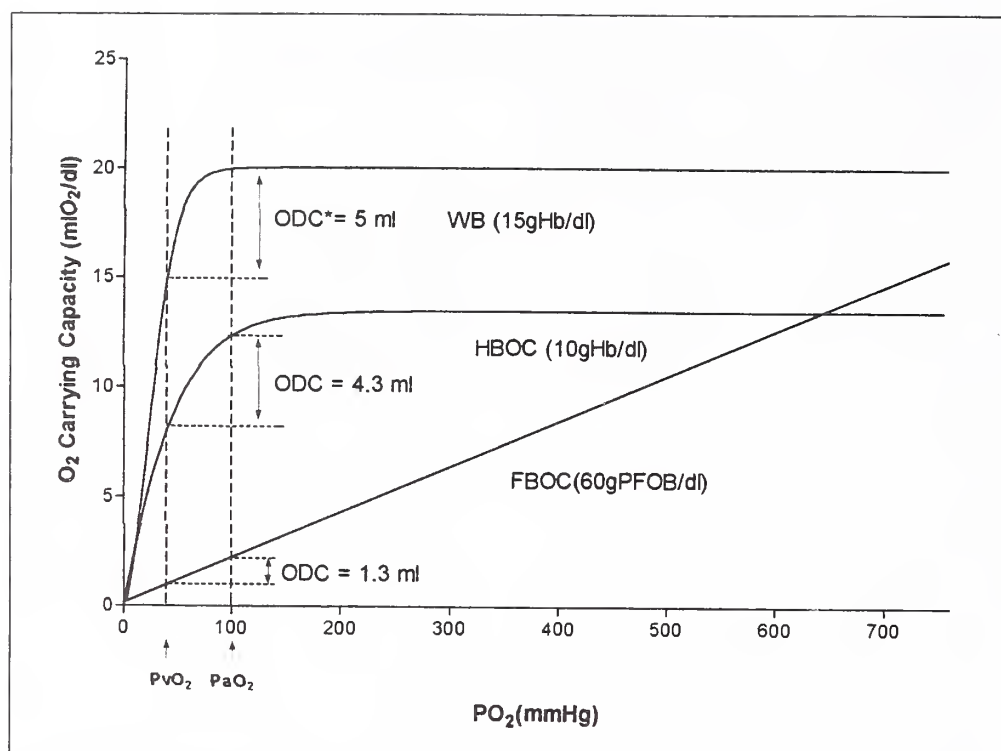


Figure-1. Oxygen carrying and delivery capacities of whole blood (WB), a typical hemoglobin-based oxygen carrier (HBOC) and a fluorocarbon-based oxygen carrier (FBOC) at varying blood oxygen tension (PO_2).

* ODC: Oxygen delivery capacity (mlO_2/dl); PFOB: perfluoro octyl bromide PaO_2 : arterial oxygen tension; PvO_2 : venous oxygen tension

tute for red cells has been around for many decades. Initial attempts to use hemolysates or crude hemoglobin solutions were hampered by a resultant toxicity to the kidneys. The primary causes of the observed Hb nephrotoxicity were found to be incomplete removal of erythrocyte stromal lipids and contamination with endotoxin and other materials. Hb solutions prepared free of stromal lipids (stroma-free Hb or SFH) were tested without any significant nephrotoxicity. However, by mid 1970s two problems were encountered with SFH. First, due to lack of DPG in solution, SFH has a higher oxygen affinity than normal intra-erythrocytic Hb (P_{50} of 10-15 torr versus 26-28 torr); oxygen offloading characteristics were perceived as inadequate. Secondly, SFH has a short, concentration-dependent intravascular circulation half-time ($t_{1/2} < 1.5$ hr); naturally tetrameric Hb ($\alpha_2\beta_2$) dissociates readily into $\alpha\beta$ dimers which are rapidly filtered through the kidneys and excreted.

"ENGINEERED" HBs

The HBOCs in clinical testing today are stroma-free and endotoxin-free Hbs that have been chemically or

genetically "engineered" to produce desirable oxygen offloading characteristics and extended intravascular retention time.²

One way to modulate the high oxygen affinity of SFH is to mimic the Hb-DPG interaction using functional DPG analogs attached to the Hb molecule. Pyridoxal-5'-phosphate, a DPG analog with a functional aldehyde residue and a negatively charged phosphate group, specifically interacts with the positively charged amino residues (e.g., Lys 82 β , His2 β , His143 β of the DPG binding site (β -pocket) to form a Schiff linkage which, upon reduction, becomes a stable covalent bond. Pyridoxalated SFH (PLP-Hb) has a near normal oxygen affinity (P_{50} = 22-24 mmHg) but is still dissociable to ($\alpha\beta$ -dimers which are susceptible to renal excretion because there is no inter-dimeric crosslink. Subsequent efforts were directed toward creating undissociable Hb molecules or Hb polymers by intra- and/or intermolecular crosslinking. SFH can be stabilized and/or polymerized using site specific or non-specific crosslinking agents. Hbs modified with site specific intramolecular crosslinkers, such as bis(3,5-dibromo salicyl)-fumarate

(DBBF or also called diaspirin) and 2-nor-2-formyl pyridoxal-5'-phosphate (NFPLP), produce low oxygen affinity Hbs with an inter-dimeric linkage between the two $\alpha\beta$ -dimers (stabilized Hb). Stabilized Hbs, such as diaspirin crosslinked-Hb (DCL-Hb) and NFPLP-Hb, do have notably increased intravascular retention times (up to 2-3 times that of SFH) but still considered inadequate. Intravascular retention times of HBOCs can be further increased by intermolecular crosslinking of stabilized Hbs using crosslinkers with bi- or poly-functional groups. For example, PLP-Hb can be polymerized using glutaraldehyde, a bifunctional nonspecific crosslinker, to produce poly(PLP-Hb) with $t_{1/2}$ of over 30 hours. A low oxygen affinity oligomeric HBOC with desirable circulation characteristics has also been produced using ring-opened raffinose (o-raffinose), a hexafunctional crosslinker. Interestingly, with this unique crosslinker, prior intra-molecular stabilization is not necessary. To circumvent the high oxygen affinity and relatively limited availability of human SFH, others have adopted low oxygen affinity animal Hb as a starting material. For example, low bovine Hb, which has a naturally lower oxygen affinity than human Hb, has been directly polymerized with glutaraldehyde without prior modification to achieve desired oxygen affinity and circulation time. Potential immunogenicity of this product is a primary concern.

Alternatively, $t_{1/2}$ of HBOCs can be extended by conjugating Hb with other macromolecules. For example, conjugation of human PLP-Hb or bovine Hb with polyethylene glycol strands (PEG-Hb) appears to protect from renal excretion. Interestingly, bovine PEG-Hb is reported to attenuate immune responses. Extending this concept further, a polyHb conjugated with anti-oxidant enzymes (e.g., superoxide dismutase and catalase) has been developed to reduce oxygen radical mediated damages.

In another approach, human or animal SFH is encapsulated in phospholipid vesicles (liposomes). For example, low oxygen affinity bovine Hb

Table 2. Clinical Trials of Potential Red Cell Substitutes

<u>Company</u>	<u>Product name</u>	<u>Description</u>	<u>Testing Phase</u>
Alliance	Oxygent	Perfluoro octyl bromide emulsion with egg yolk lecithin	II
Baxter	HemAssist (DCL-Hb)	Human Hb crosslinked with diaspirin between α subunits	III*
Somatogen	rHb1.1 (Optro)	Recombinant human Hb produced in E. coli	II**
Biopure	Hemopure (HBOC-201)	Bovine Hb polymerized with glutaraldehyde	III
Enzon	PEG-Hb	Bovine Hb conjugated with polyethylene glycol	II
Hemosol	Hemolink	Oligomeric human Hb modified with o-raffinose	II
Northfield	PolyHeme	Human Hb pyridoxalated and polymerized with glutaraldehyde	III

* All clinical trials suspended

** Acquired by Baxter

along with reducing agents is encapsulated in liposomes (LEH-Hb). Heme also has been imbedded between two lipid bilayers to produce similar effects. More recently, biodegradable nanocapsules containing Hb and enzymes (e.g., carbonic anhydrase and catalase) have been developed. Although conceptually intriguing, these liposomal or embedded Hbs are reported to activate the complement system, are rapidly cleared by the reticuloendothelial system and may interfere with the normal immune function.

With recent advances in recombinant DNA technologies, native or specifically modified Hbs may be produced from microorganisms (E. coli, yeast, etc.), transgenic plants or animals. Prestabilized recombinant human Hb has been produced in E. coli and S. cerevisiae using an expression vector containing two mutant human globin genes, one with a low oxygen affinity mutant and another tandemly fused alpha globins. Human Hb has also been produced in transgenic animals. Human alpha and β globin gene constructs are injected into newly fertilized mouse or pig eggs and the resultant embryo developed in a surrogate mother. Red cells of transgenic animals thus born contain authentic human Hb. Harvesting and purification of desired Hb product

from these animals is, however, more complicated since the red cells contain hybrid Hbs as well as animal's own and human Hbs. Economics and effectiveness of this approach is yet to be tested.

Some of the key approaches in HBOC development are summarized in Table 1.

The need for a red cell substitute, a surrogate for the allogeneic blood of today, is real. Indeed, if one such substitute were available, as much as 60% of the current use of allogeneic red cells could be eliminated in the surgical environment alone.



CLINICAL TRIALS OF RED CELL SUBSTITUTES

Currently, some eight different red cell substitutes are in various stages of development. Of these, six HBOCs and one FBOC are being currently tested in clinical trials (Table 2). These

substitutes differ in many aspects including the nature of the active ingredient (Hb or perfluorochemical), concentration, physicochemical properties, preparation methods and source of raw material. It is, thus, unreasonable to expect them to have the same effects on the human subjects.

A 60% (w/v) perfluorooctyl bromide emulsion based FBOC has been tested in Phase I and II studies and is currently being tested in extended Phase II clinical trials. In the initial studies, incidences of delayed febrile responses and thrombocytopenic episodes were reported.⁵ The cause(s) of these adverse effects have not been identified. Because perfluorinated carbons, in general, are chemically very stable, potential long term biological effects including absorption, distribution, metabolism, and excretion and effects on the reticuloendothelial system should be studied. Further, since the emulsifier used in this FBOC preparation is egg yolk phospholipid, its effects on lipid and cholesterol metabolism and the cardiovascular and other systems are also of concern.

To date six different HBOCs have been tested in more than 1,000 subjects in the U.S., Canada, and Europe. PolyHeme (Northfield Laboratories, Evanston, IL), a pyridoxalated and polymerized Hb, has completed Phase II studies and is currently being evalu-

ated in Phase III studies.⁶ PolyHeme transfusion following an acute hemorrhage is reported to be as effective as allogeneic transfusion in maintaining total Hb concentration and have less allogeneic transfusion.

DCL-Hb, a human Hb crosslinked with diaspirin (Baxter, Dearfield, IL), has been tested in phase III trial involving 209 cardiac bypass patients. In this study, 59% of patients who were judged as requiring a transfusion and given DCL-Hb infusion instead could avoid transfusion during the first day of surgery.⁷ Two additional DCL-Hb Phase III studies, one in the U.S. one in Europe, had been initiated to assess efficacy of DCL-Hb in patients with severe trauma and shock. Because of a lack of clear efficacy (improved mortality rate), both of these studies have been suspended pending further analysis.

Hemolink, a Hb modified with o-raffinose (Hemosol, Mississauga, Ontario, Canada), is currently tested in Phase II trials in patients undergoing an elective surgery.⁷ In these initial trials, Hemolink is given following presurgical autologous blood donation and when blood transfusion is required during or after the surgery, the patient's own blood is transfused. A significant reduction in the need for blood transfusion with Hemolink pre-infusion would indicate efficacy. Hemosol is focusing on at least three clinical applications: a hemodiluent in elective surgery, a blood transfusion alternative in trauma and emergency surgery, and an erythropoiesis stimulant in some forms of chronic anemia.

HBOCs based on bovine Hb are also being tested in clinical trials. Hemopure (Biopure, Boston, MA), a bovine Hb polymerized with glutaraldehyde, has just been cleared for a multi-center phase III study. In this study, perioperative uses of Hemopure as an alternative to red cell transfusion will be explored in elective orthopedic surgical cases. Bovine Hb conjugated to polyethylene glycol (PEG-Hb; Enzon, Piscataway, NJ) has been tested in Phase I safety testing in healthy volunteers and is undergoing escalating multiple dose trial in cancer patients.⁸

Adverse responses thus far revealed in HBOC clinical trials are generally mild in nature including a moderate change in cardiovascular and gastrointestinal systems; yet, no serious toxicities directly attributable to HBOC have been reported. The most common adverse response is a mild transient hypertension although DCL-Hb was using the presser effect as part of its objective. Other untoward effects include esophageal discomfort, flu-like symptoms, elevated enzymes levels (e.g., amylase, lipase, LDH-5, CK), and jaundice-like discoloration of the skin and eyes. The exact causes of these reactions have not been elucidated. The hypertension and esophageal problems may be, in part, related to the extremely high affinity of Hb for nitric oxide (NO), a vasodilator and a neurotransmitter. In the vascular system, HBOC could scavenge the constitutively expressed endothelium derived NO causing vascular smooth muscle to contract.⁹ The esophageal spasm observed with some HBOCs may also have been caused by Hb interaction with NO. In the lower esophagus, NO is secreted by non-adrenergic non-cholinergic neurons to coordinate rhythmic contraction of circular smooth muscles. Hb interaction with this neuronal NO might have altered the normal esophageal motility. Exactly how Hb interacts with these NO is still mystery and requires further studies.

Above is a brief review of some representative approaches to red cell substitutes. Further information on this subject can be found in recent reviews by authors^{2,7} and Chang.¹⁰

THE FUTURE

Predicting the future can be fraught with danger. The ability to predict changes in medical practice and the implication of innovations on practice patterns and costs is not an exact science.

There is little doubt that concerns about the safety of red cell transfusion remain in the physician and patient populations. The desire to avoid allogeneic transfusion is real and a valid goal of modern therapeutics. The uses of paradigms that explore other aspects

of the oxygen delivery system so that tissue perfusion is optimized or maximized before the consideration of a red cell transfusion is made are now valid and acceptable practice models. As the whole of cardiopulmonary physiology is made clearer and the limits of "anemia" are defined - here anemia holds the traditional definition of a low hemoglobin concentration or hematocrit - the role of manipulating the parameters of the oxygen delivery system as a means of transfusion avoidance becomes real. The need for a red cell substitute, a surrogate for the allogeneic blood of today, is real. Indeed, if one such substitute were available, as much as 60% of the current use of allogeneic red cells could be eliminated in the surgical environment alone. The implications are real and the end desirable.

This article addresses some of the issues and options for red cell replacement that are directed at decreasing the use of allogeneic red cells. Just consideration of the physiologic manipulation options and acceptance of a lower "transfusion trigger" would have an impact. The substitutes of the future are more complex. We are only dealing with the first generation of products and already there are casualties by the roadside - solutions that were the victims of rapid testing and overconfidence in the product that have failed in the clinical arena at the crucial Phase III level efficacy. The basis for the failure is not yet clear. Second and third generation solutions will be tailored for specific indications and may be much more complex in composition. The issue with liposomes may be overcome and conjugates with enzymes directed at specific physiology may be realistic.

Thus the options for the future of red cell transfusion include changes in transfusion practice based on knowledge and not lore and tradition, an appreciation of the limits of the cardiopulmonary system with reference to age and physiologic status of the patient, tempered by the pharmacologic treatment of the patient and the use of solutions that carry and deliver oxygen to tissues. These solutions will be used

by themselves or in combination with other approaches that are directed at red cell conservation and autologous red cell use, the sole aim being to decrease the exposure to allogeneic red cells.

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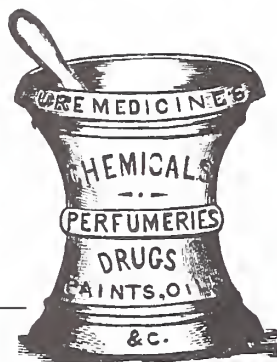
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Advances in Pharmacology

New Medication Options for Patients with Epilepsy

Andrew N. Wilner, MD, FACP

Epilepsy is a group of diseases characterized by recurrent seizures, affecting as many as 3% of the population in North America.¹ Epileptic seizures are abnormal synchronous electrical discharges from specific neuron populations. The precise location of these neuron clusters determines a patient's symptoms. Abnormal electrical discharges can be best viewed with an electroencephalogram (EEG) during a seizure. Brain injury of many types can result in recurrent seizures. Common etiologies of the epilepsies are head injury, encephalitis, meningitis, genetic, hemorrhagic and ischemic infarcts, and brain tumors.

Since 1993, five drugs have been approved by the Food and Drug Administration for the treatment of epilepsy; felbamate (Felbatol), gabapentin (Neurontin), lamotrigine (Lamictal), topiramate (Topamax) and tiagabine (Gabitril).² In addition to these new compounds, improved versions of several well known antiepileptic drugs (AED) have also become available. These new drugs and formulations offer the potential for improved seizure control and less disagreeable side effects. The proven value of these medications comes as a result of enormous

efforts by pharmaceutical companies, clinical researchers, and willing patients.

To aid in the management of patient with acute seizures, a less toxic and water soluble phenytoin (Dilantin) has been approved: fosphenytoin (Cerebyx). An intravenous form of divalproex sodium (Depakote) is also available for patients who cannot take medication by mouth due to gastroenteritis or surgery. Two long-acting preparations of carbamazepine are now available: Tegretol XR and Carbatrol. Tegretol XR slowly releases carbamazepine from a capsule with a special osmotic membrane. Carbatrol contains three different kinds of beads which dissolve at specific times in the stomach and small intestine.

Diastat, a diazepam gel, can be inserted rectally in patients with seizure clusters to limit trips to the emergency room. Caregivers need to be trained to administer the preparation and monitor vital signs.

Most epileptic seizures are either "partial," beginning in one area of the brain, or "generalized," beginning in all areas of the brain simultaneously. Partial seizures may remain restricted to a small area or "focus," producing symptoms which correlate with the anatomical localization. For example, unformed visual hallucinations such as spots occur with occipital seizures. Formed hallucinations such as images of people or a train come from the posterior temporal lobe. Déjà vu phenomena, feelings of familiarity, originate from

Abbreviations Used:

AED	antiepileptic drugs
EEG	electroencephalogram

the mesial temporal lobe.

Seizures are termed "partial simple" if consciousness remains unimpaired. When seizures begin focally, and consciousness becomes impaired, seizures are termed "partial complex." Partial seizures may also spread and become tonic-clonic, in which case they are referred to as partial seizures with secondary generalization.

Seizures of partial origin respond well to medications such as phenytoin (Dilantin), carbamazepine (Tegretol) and divalproex sodium (Depakote). For primary generalized epilepsy, such as absence seizures and convulsions which do not have a single focus, divalproex sodium (Depakote) is preferable.

THE NEW ANTIEPILEPTIC DRUGS

Felbamate is approved as monotherapy or adjunctive treatment of refractory partial seizures, as well as for adjunctive treatment of Lennox Gastaut syndrome. It is the only one of the five new drugs approved for monotherapy. Its most common side effects are anorexia, weight loss, and insomnia. However, approximately 1:5,000 patients develop aplastic anemia; 1 in 34,000 develop hepatic failure. Consequently, the drug is now reserved only for the most difficult epilepsy cases where the benefit of controlling recurrent seizures warrants the risk of these potentially fatal side effects.

Gabapentin, like lamotrigine, tiagabine, and topiramate, is indicated



for the adjunctive therapy of partial seizures in adults. Its mechanism of action is unknown. Gabapentin's metabolism is unique in that it is entirely eliminated by the kidneys. Consequently, there is no enzyme induction in the liver, a common phenomenon which occurs with many of the older antiepileptic drugs such as carbamazepine, phenytoin, and phenobarbital. Gabapentin has no known drug interactions, making it an attractive compound for use in the elderly, who often ingest multiple medications.

Lamotrigine acts on sodium channels, inhibiting the release of the excitatory neurotransmitter glutamate. Carbamazepine and phenytoin shorten lamotrigine's half life, while valproate can markedly increase it. Consequently, when used with enzyme inducing agents, a different dosing schedule must be followed than when used with valproate. The most troublesome side effect of lamotrigine is rash, which occurs in approximately 10% of patients.³ This rarely evolves into the serious Stevens-Johnson syndrome. (When patients report a rash, I examine them to confirm that it is a drug eruption. If so, I stop the lamotrigine immediately and observe the patient closely over the next few days.) Lamotrigine has recently been approved as adjunctive therapy for generalized seizures of Lennox-Gastaut syndrome in pediatric and adult patients.

Tiagabine inhibits the reuptake of gamma-aminobutyric acid and consequently increases the amount of this inhibitory neurotransmitter at the synapse. Tiagabine does not appear to affect the levels of other drugs. It is highly protein bound. Side effects are mostly dose-related symptoms such as dizziness, tremor, and asthenia.

Topiramate has at least three mechanisms of action; a sodium channel blocker, enhancer of gamma-aminobutyric acid neuroinhibition, and a blocker of glutamate excitation. Topiramate is also a carbonic anhydrase inhibitor, a possible fourth mechanism of action. This last property can also result in the side effects of paresthesias (15%) and renal stones (1.5%). Clinical trials with topiramate suggested that 1 in 3 patients with refractory epilepsy will improve significantly with the addition of topiramate to their regimen. A small number of patients (4-9%) became seizure free.

Although many patients can be helped by these new drugs, the most common cause of seizure recurrence is non-compliance with a prescribed regimen. Patients should always have drug levels checked before switching to another medication if compliance is in doubt. Medication compliance improves with fewer daily doses which creates a role for the newer long acting preparations such as Tegretol XR and Carbatrol. Lamotrigine, tiagabine, and topiramate are also prescribed on a twice a day schedule. Gabapentin is best prescribed three times a day due to its short half-life. In addition, patients with mild epilepsy can often be maintained on one nightly dose of phenytoin.

The new AEDs represent a significant advance in the treatment of the epilepsies. They also add an additional level of complexity in managing patients with difficult-to-control seizures. With the pending approval of at least two other AEDs (vigabatrin and oxcarbazepine), therapeutic

options will increase further.

As of today, there is no clear "best" drug or drug combination for the treatment for patients with epilepsy. The management of each patient must be individualized with respect to seizure type, side effect profile, and potential drug interactions. Monotherapy is still the preferred approach when possible.

As physicians gain experience with these medications in clinical practice, and with continuing clinical trials, more information on the efficacy and tolerability of these drugs will emerge. Although complete seizure freedom remains elusive for many patients, these new antiepileptic drugs can succeed in propelling some of them towards that goal.

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Disparities in Mortality Among Racial and Ethnic Groups

Jay S. Buechner, PhD

The President's Initiative on Race is founded on compelling evidence that there are persistent and, in some cases, increasing disparities in health status among the nation's populations defined by race and ethnicity. In response, the U.S. Department of Health and Human Services has established the goal of eliminating racial and ethnic disparities in six key areas of health status:

- Infant mortality
- Cancer screening and management
- Cardiovascular disease
- Diabetes
- HIV infection
- Child and adult immunization

In this analysis, mortality rates for Rhode Island covering four of these areas are presented by race and ethnicity for the period 1993-1997 in order to determine the extent of health status disparities in the state. In addition, these mortality rates are compared to rates for the period 1998-1992 to determine whether the levels of disparity have increased or decreased.

Methods

Data on mortality among Rhode Island residents were aggregated from Vital Statistics Death Files by age group, race, ethnicity, and cause for two time periods, 1988-1992 and 1993-1997. Data for the years 1995-1997 are preliminary and subject to change. Four causes of death were examined: cancer, heart disease, diabetes, and AIDS. Five race/ethnic origin groups were used: Hispanic, African American, Asian/Pacific Islander, American Indian, and non-Hispanic White. Because race and ethnic origin are collected independently on the death certificate, some decedents identified as Hispanics may also have been included in the racial categories African American, Asian/Pacific Islander, and American Indian. Deaths were aggregated to eleven age groups for the purpose of age-standardization, including under 1 year, 1 to 4, 5 to 14, 15 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, 65 to 74, 75 to 84, and 85 years and older. Using Bureau of the Census population

estimates for Rhode Island for 1990 and 1995, average annual mortality rates by cause and by race/ethnicity were computed, age-adjusted to the 1940 United States standard million population.

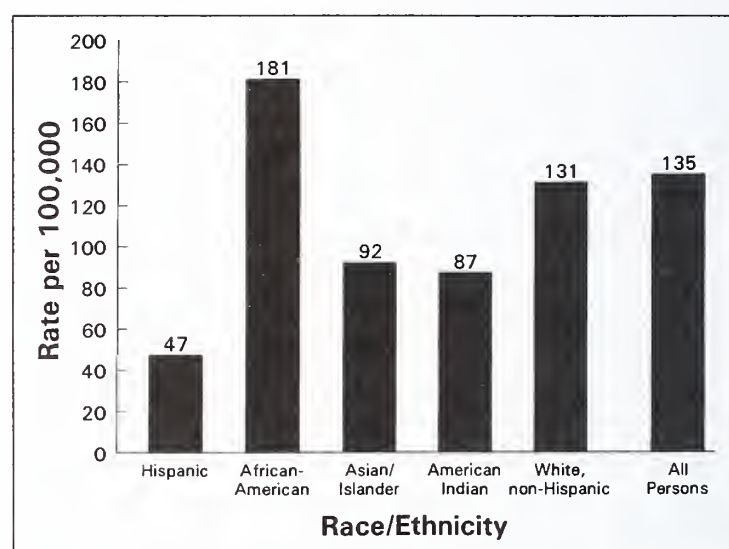


Figure 1. Deaths from Cancer per 100,000 Population (Age-Adjusted), Rhode Island, 1993-1997 Average.

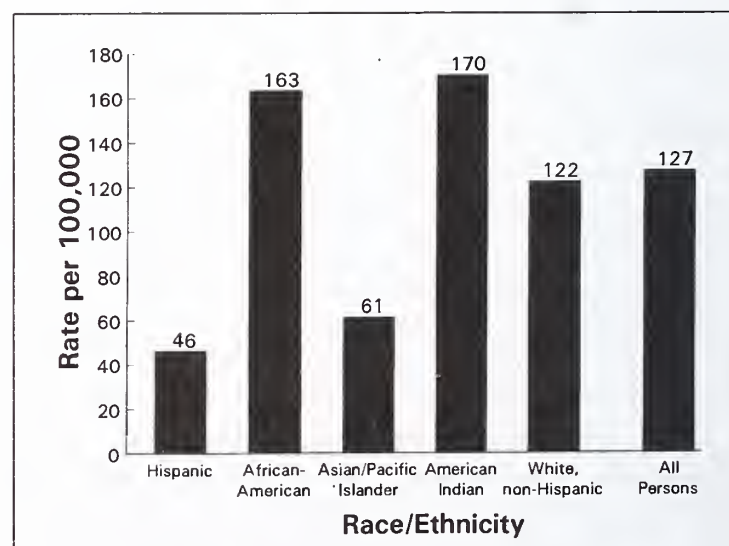


Figure 2. Deaths from Heart Disease per 100,000 Population (Age-Adjusted), Rhode Island, 1993-1997 Average.

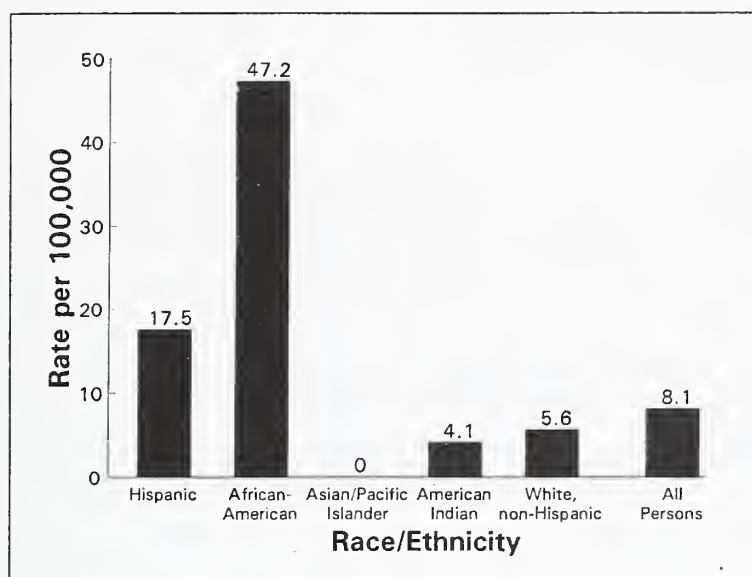


Figure 3. Deaths from AIDS per 100,000 Population (Age-Adjusted), Rhode Island, 1993-1997 Average.

Results

For each of the four causes of death, one or more racial or ethnic minority groups in the state experienced elevated mortality rates for the period 1993-1997. For cancer, the mortality rate for African Americans was 34% higher than the state rate; all other minority groups had rates lower than the state rate and lower than the rate for non-Hispanic Whites. (Figure 1) For heart disease, both African Americans (28% higher) and American Indians (34% higher) showed higher than average mortality. (Figure 2)

The statewide mortality rates for AIDS and diabetes are much lower than for cancer and heart disease, but the disparities between racial/ethnic groups are relatively larger. For AIDS, mortality among African Americans is nearly six times the state rate; for Hispanics it is over twice the state rate. (Figure 3) Diabetes mortality is three times the state average for African Americans and over twice the state average for American Indians. (Figure 4)

For both of the major chronic disease causes of death, the statewide mortality rates declined from 1988-1992 to 1993-1997. Over the same period, the amount of excess mortality seen among minority racial and ethnic minori-

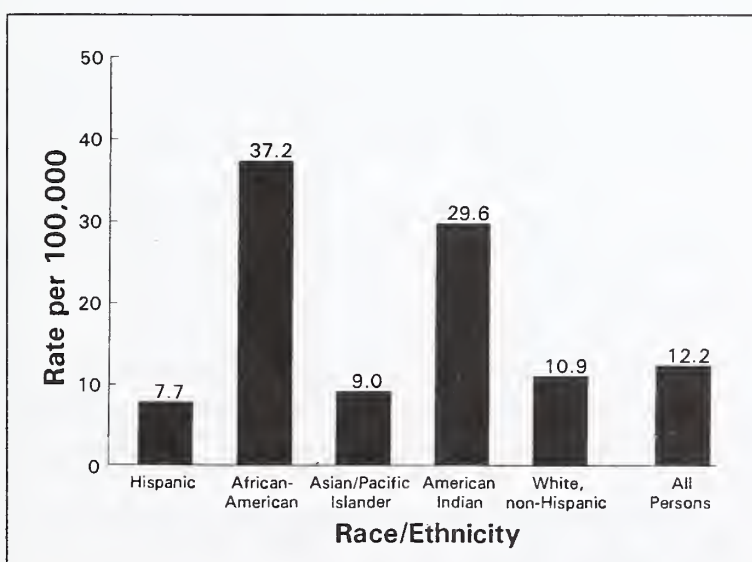


Figure 4. Deaths from Diabetes per 100,000 Population (Age-Adjusted), Rhode Island, 1993-1997 Average.

ties generally declined as well, reducing the disparities relative to the state average. For example, cancer mortality among African Americans fell by 9% compared to the 5% decline in the mortality rate for the state as a whole. For heart disease, the rate for African Americans fell by 15%, and the overall rate fell by 11%. However, the heart disease mortality rate for American Indians rose by 45%, a large relative increase, but based on a small change in the actual number of deaths.

Statewide mortality rates for both AIDS and diabetes rose between the two time periods, by 25% for AIDS and by 4% for diabetes. AIDS mortality for both African Americans (up 29%) and Hispanics (up 54%) increased more rapidly than the statewide rate. For diabetes, the African American grew by 15%, but the American Indian rate fell by 25% from one five-year period to the next.

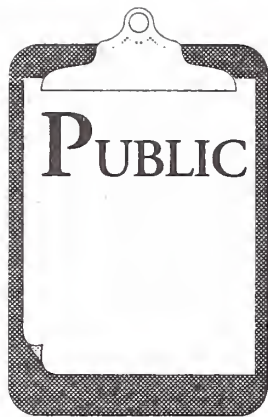
Discussion

Examination of the mortality rates for these four conditions identified in the President's Initiative reveals that the disparities found at the national level are often reflected in Rhode Island's data. Locally, African Americans in particular appear to be at elevated risk, with mortality excesses for all four causes. Also, Hispanics and American Indians showed excess mortality from one or more causes.

National health objectives for the year 2000 were established based on goals that included the reduction of health disparities, including those among populations defined by race and ethnicity. For the year 2010, health objectives are being developed based on the more ambitious goal of eliminating such disparities, in part because of the equity inherent in such a goal, but in part because populations experiencing poorer health status are expected to grow in their proportion of the nation's population. Therefore, improvements in health status for the population as a whole will depend increasingly on improvements among disadvantaged populations.

The same is true for Rhode Island, where the percentage increases in our Hispanic and Asian/Pacific Islander populations between the census years 1980 and 1990 were the largest for any state, and where all minority groups continue to grow in this decade while our total population has fallen. Reducing health disparities in the state such as those presented here for mortality will require improvements in preventing disease, promoting health, and delivering appropriate health care for all members of our population.

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HEALTH BRIEFING

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by John P. Fulton, PhD

Cancer Control Rhode Island: Strategic Plan for 1998-2005

John P. Fulton, PhD, and Donald K. Perry, MPA

Cancer is a serious health threat in Rhode Island, killing over 2000 people and costing over \$450 million annually. Nonetheless, since the State's first cancer control plan (1989), increased knowledge in cancer prevention, detection, and treatment has led to progress in cancer control.

THE CANCER CONTROL PLANNING PROCESS

The Director of Health convened a Planning Task Force of Rhode Island cancer control experts and Health Department staff to revise the State's cancer control plan, used by the Department and the community to guide cancer control interventions. Task Force recommendations were published in *Medicine & Health / Rhode Island* for readers' comments, which were incorporated into final recommendations. The resulting draft plan was circulated throughout the State for final review and refinement prior to its adoption in September, 1998. The plan is a dynamic document, subject to ongoing public review.

SUMMARY OF FINDINGS

Rhode Island bears a significant cancer burden. Over 5000 cases of cancer are diagnosed each year. Cancer accounts for about 2500 of the State's 10,000 annual deaths, and costs the State roughly \$453 million in medical and lost opportunity costs annually. Rhode Island's cancer burden has a distinctly urban profile, characterized by higher than average mortality from cancers related to diet (e.g., stomach and colon-rectum), cancers in which diet is implicated (e.g., breast and prostate), and cancers related to tobacco use (e.g., lung and bronchus, urinary bladder, esophagus, oral cavity, pharynx and larynx). Paralleling national data, African Americans were about one-third more likely than whites to die of cancer in Rhode Island during the 1980s.

Rhode Island has made recent progress in adopting preventive behaviors and screening tests. Fewer Rhode Islanders smoke, and progress is being made in women's cancer screening. Nonetheless, the prevalence of preventive behaviors and the use of screening tests is still too low, especially among people of low socio-economic status (s.e.s.).

Major barriers to cancer control include poorly developed communication channels between cancer control professionals and people of low s.e.s., insufficient primary care resources for people of low s.e.s., misunderstandings about

clinical trials in the population at large and distrust of clinical trials among minority groups, and the inaccessibility of Hospice care to many terminally ill cancer patients, especially those of low s.e.s.

Cancer control surveillance is well developed in Rhode Island. The Behavioral Risk Factor Surveillance System (an ongoing survey of adult Rhode Islanders), the cancer registry, and the vital registration system all contribute timely and accurate data for cancer control planning and evaluation. The plan recommends low-cost enhancements for these systems.

SUMMARY OF RECOMMENDATIONS

Screening recommendations were developed for cancers of the colon-rectum, female breast, cervix, oral cavity, prostate, and skin (Table 1).

Three top priorities have been selected for immediate intervention: to communicate cancer control recommendations more effectively to people of low s.e.s., to develop primary care resources to meet the cancer control needs of people of low s.e.s., and to develop regular, ongoing professional education of primary care providers to assure timely awareness and understanding of changing cancer control recommendations.

Three top priorities have been selected for additional planning: to develop more effective cancer control interventions in primary care settings, to increase the use of clinical trials in the treatment of adult cancer patients, and to increase the use of hospice services by terminally ill cancer patients.

Cancer Control Rhode Island: Strategic Plan for 1998-2005 is available web site of the Rhode Island Department of Health: "www.health.state.ri.us" under "The Rhode Island Cancer Registry." A paper copy may also be requested from the author by fax (401-861-5751) or by mail (John Fulton, RI Department of Health, 3 Capitol Hill, Providence, RI 02908-5097).

John P. Fulton, PhD, is Acting Associate Director, Division of Disease Prevention and Control, Rhode Island Department of Health, and Clinical Associate Professor, Brown University School of Medicine.

Donald K. Perry, MPA, is Supervising Health Planner, Rhode Island Department of Health.

Table 1. Screening recommendations

Cancer of the colon-rectum

- All persons should receive an annual digital rectal examination beginning at age 40.
- All persons 50 years of age and over should receive fecal occult blood testing annually and flexible sigmoidoscopy every 5 years. Persons positive by either screening test should be referred for colonoscopy.
- Persons at elevated risk for the development of colorectal cancer should be referred for diagnosis and management if there is:
 - a family history of hereditary syndromes associated with a high incidence of colon cancer (polyposis syndromes),
 - at least one first degree relative with colorectal cancer,
 - a personal history of colon adenomas or colon cancer,
 - inflammatory bowel disease involving the colon.

Cancer of the female breast

- For women without a family history of pre-menopausal breast cancer, CBE should be performed at the periodic health examination after the age of 30.
- Annual CBE and mammography after age 40.
- For women with a first degree relative diagnosed with pre-menopausal breast cancer, annual mammography should commence 5-10 years prior to the age at which the relative was diagnosed.
- Women with BRCA1 and BRCA2 mutations should commence monthly BSE by 20 years of age, and should receive annual or semiannual CBE, and annual mammography, beginning at age 25 to 35 years.

Cancer of the cervix

- For women in high risk groups — women with multiple sex partners, sexually promiscuous partners, early age at first intercourse, and/or a history of a sexually transmitted disease (including human papilloma virus) — Pap smears should be performed annually.
- For women who are HIV positive, Pap smears should be performed at least annually.
- For asymptomatic women with a cervix and no risk factors, regular Pap smears should be performed if a woman is or has been sexually active. There is no upper age limit for the performance of regular Pap smears.
- If a history of past and/or present sexual activity cannot be accurately determined and a woman is 18 years of age or over, routine Pap screening should be initiated.
- Women who have had a hysterectomy cannot be presumed to be without cervical tissue and the decision to screen them with Pap smears should be determined on a case by case basis.

Cancer of the oral cavity

- Primary care providers should remain alert to the signs of early oral cancer, particularly leukoplakia and erythroplakia, and should refer patients with these lesions to a surgical specialist for further evaluation and treatment.

Cancer of the prostate

- Primary care providers should inform men ages 45 and over about the known risks and potential benefits of prostate cancer screening with the PSA and DRE, and make available annual screening with PSA and DRE to men ages 50 and over with at least a 10-year life expectancy and to men ages 45 and over with a high risk of developing prostate cancer (i.e., men with a family history of prostate cancer and African-American men) who, after considering information about the known risks and potential benefits of prostate cancer screening, request to be screened.

Cancer of the skin

- Do not recommend for or against routine screening for skin cancer by primary care providers.
- Clinicians should remain alert for skin lesions with malignant features (i.e., asymmetry, border irregularity, color variability, diameter > 6mm, or rapidly changing lesions) when examining patients for other reasons, particularly patients with established risk factors, including clinical evidence of melanocytic precursor or marker lesions, large numbers of common moles, immunosuppression, a family or personal history of skin cancer, substantial cumulative lifetime sun exposure, intermittent intense sun exposure or severe sunburns in childhood, freckles, poor tanning ability, light skin, hair, and eye color.
- Recommended to consider referring patients at substantially increased risk of malignant melanoma to dermatologists specializing in skin cancer for evaluation and surveillance. Persons at substantially increased risk for malignant melanoma include those with melanocytic precursor or marker lesions, e.g., atypical moles [also called dysplastic nevi], certain congenital nevi, familial atypical mole, and melanoma syndrome.



Health Care Quality Improvement in Rhode Island: Community Acquired Pneumonia

Liudvikas Jagminas, MD, FACEP, and Lawrence Proano, MD FACEP

There are an estimated 4 million cases of community-acquired pneumonia (CAP) reported annually in the United States, with an attack rate of 12 per 1,000 adults per year. This results in about 600,000 hospitalizations, and an annual cost of \$23 billion.¹⁻⁵ In Rhode Island, CAP was the second most common DRG for in-patient hospitalizations of Medicare patients. From October 1995 to October 1996 there were 2009 discharges for CAP with a total of 16,682 hospital days. Nationwide, pneumonia is the leading cause of death from infectious illness and the sixth leading cause of death in the United States.³ Among elderly patients, it is the fourth leading cause of death.^{5,6}

ETIOLOGY

The etiologic pathogens of CAP have changed over time; however, the percentage of patients with an unknown microbial diagnosis remains at nearly 50%.^{3,7} In the 1990s, the number of organisms implicated in CAP increased to include *H. influenzae*, *C. pneumoniae*, *Legionella* species, *Moraxella catarrhalis*, and gram-negative bacilli. Based on the review of 15 published articles from North America that span 3 decades, Bartlett and Mundy report the ranges for the prevalence of the following pathogens: *S. pneumoniae* 20-60%; *H. influenzae* 3-10%; *S. aureus* 3-5%; *Legionella* 2-8%; *M. pneumoniae* 1-6%; *C. pneumoniae* 4-6%; gram-negative bacilli 3-10%; vi-

ruses 2-13%; aspiration 6-10%; and miscellaneous 10-20%.⁸

CAP IN ELDERLY PATIENTS

The elderly have a heightened risk for CAP. The incidence rises steadily for individuals over the age of 50, with a 10-fold increase in those aged 70-79 years vs. those aged 20-29 years of age.⁹ Hospitalization also increases with age, from 0.35/1,000 adults aged 20-29, to 1.35/1,000 for those between 65-75 years of age, and to 11.6/1,000 for those aged 75 years and older.¹⁰ Patients over the age of 65 without such comorbid conditions have a pneumonia death rate of 9/100,000; this rate increases to 217/100,000 in persons with one risk factor, and to 979/100,000 in persons with two or more risk factors.¹¹

UTILITY OF DIAGNOSTIC TESTING

Tests most commonly used to identify the causative organism in CAP

Abbreviations Used:

ATS	American Thoracic Society
CAP	community-acquired pneumonia
CME	continuing medical education
DRG	diagnostic related group
RIQP	Rhode Island Quality Partners

are the sputum gram-stain, sputum culture, blood culture, serology for specific pathogens, antigen detection methods, and fiberoptic bronchoscopy.^{3,12} The number of cases where the causative agent in CAP can not be identified is significant, and the usefulness in establishing the etiologic agent of CAP by these tests has been challenged.^{13,14,15} The diagnostic value of expectorated sputum in identifying the causative agent is uncertain and highly debated.^{16,17} Blood cultures are not useful in guiding initial therapy, but may be useful if the patient is not responding to the course of treatment. This is underscored by the results of a study by Chalasani et al. where only 6.6% of 517 patients had positive blood cultures, and only 1.4% of those

Baseline measurement	Oxygen assessment	Blood cultures within 24 hours	Blood cultures before antibiotics	Antibiotic Timing (median delay)
Statewide	94%	76%	62%	4.7 hours
National	89%	69%	57%	4.3 hours

Figure 1.

	Oxygen assessment	Blood cultures within 24 hours	Blood cultures before antibiotics	Antibiotic Timing (median delay)
Baseline measure	94%	76%	62%	4.7 hours
Remeasurement	98%	80%	67%	3.8 hours

Figure 2.

required a change in antibiotic therapy.¹⁸

CAP AND MORTALITY

The mortality for CAP is between 1% and 5% for outpatients and up to 30% or higher in severely ill, hospitalized patients.³ In a meta-analysis of 33,148 patients with community-acquired pneumonia the overall mortality was 13.7%.¹⁸

IMPORTANCE OF EARLY TREATMENT

Early initiation of empiric therapy can avoid delays that are inherent in procedures accompanying the hospital admission process. Clinical studies are limited regarding this issue, and the ATS guidelines do not address it. Delay to therapy of up to 6-8 hours or longer may occur between the time of the decision to admit the patient with CAP and the administration of the first intravenous dose of antibiotics. Based on observational data, mortality due to delay in the first dose of antibiotics reached statistical significance at 7 hours after hospital arrival.¹⁹

In Rhode Island, all 10 acute care hospitals, in collaboration with Rhode Island Quality Partners (RIQP) participated in a CAP Project. The objective of the project was to reduce the morbidity, mortality, and resource consumption associated with CAP. The project collected the following quality improvement indicators identified as important by literature review and expert panel consensus for analysis; (1) oxygenation assessment within 24 hours of arrival; (2) blood culture collection within 24 hours of arrival; (3) blood culture collection before initial hospital antibiotics; and (4) timing of initial antibiotic administration.

Based on observational data, mortality due to delay in the first dose of antibiotics reached statistical significance at 7 hours after hospital arrival.¹⁹

At baseline, a total of 446 patients with CAP were abstracted and 288 met all confirmatory criteria for study inclusion. Performance in Rhode Island was consistent with the national average with a median delay to first dose of

antibiotics of 4.7 hours and with 25.6% of patients receiving their first dose 8 hours after hospital arrival (Table 1).

A quality improvement project was undertaken to improve the time to antibiotic administration, as well as increase the utilization of the other indicators. A CME monograph abstracting multiple articles related to the diagnosis and treatment of CAP was sent out to all internists, family and emergency physicians in Rhode Island. In addition, the baseline performance data was shared with the acute care hospital community. Opportunities for improvement in performance indicators were identified and prompted the use of clinical pathways, standing orders, and educational activities.

Remeasurement after the implementation of the QI opportunities and CME monograph identified 1326 cases of CAP with 973 meeting all confirmatory criteria for inclusion. All 4 QI parameters showed improvement (Table 2), most importantly the median time to antibiotic administration dropped from 4.7 hours to 3.8 hours accompanied by decreases in mortality from 12.9% to 10.1% and average length of stay from 9.5 to 8.1 days ($p < .01$).

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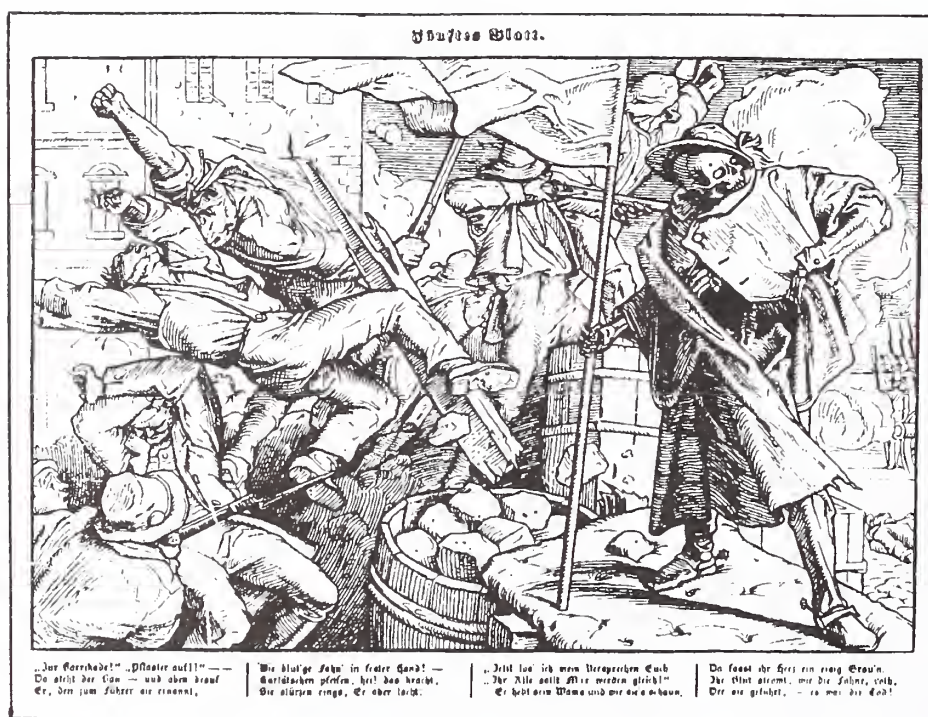
The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Health Care Financing Administration, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

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CLINICAL TRIALS DIRECTORY

Medicine & Health/ Rhode Island is pleased to launch this Directory. In Rhode Island, many researchers—hospital-based and community-based—are conducting clinical trials; but the channels of communication are not optimal. We intend this Directory of Clinical Trials to serve as an information clearinghouse for ongoing trials in the state. If you would like to list a trial, please contact:

Joan Retsinas
Managing Editor
phone/fax: (401) 272-0422
e-mail: JRetsinas@aol.com.

Congenital Esotropia Observational Study

Sponsor: National Eye Institute of NIH

Purpose: Despite the common occurrence of congenital esotropia, prospective data on its early course are limited. Such data are needed to determine the earliest age at which surgery can be safely performed without concern that the esotropia is likely to resolve spontaneously. To provide these data, an observational study of congenital esotropia is being conducted by the Pediatric Eye Disease Investigator Group, a group of about 150 pediatric ophthalmologists located through North America, formed to conduct clinical research in pediatric ophthalmology.

Patients Recruited: patients, between 9 and 17 weeks of age, with a gestational age ≥ 37 weeks and birth weight > 2000 grams (4 lb, 6 oz), and who are neurologically and developmentally normal.

Intervention: an examination (identical to the pediatric ophthalmologist's usual routine, with no additional procedures performed specifically for the study), and two follow-up visits, one 2-4 weeks after the first examination, the other when the child is between 28 and 32 weeks of age.

Site: office of David Robbins Tien, MD, 110 Lockwood Street, Suite 440, Providence, RI 02903

Contact: David Robbins Tien, MD, phone: (401) 444-7008; fax: (401) 444-4862

For more information about other participating pediatric ophthalmologists, contact the PEDIG Data Coordinating Center, (888) -79PEDIG

A Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging, Study for the Safety, Tolerability and Efficacy of

S1B-1508Y in Parkinson Disease Patients who are Requiring but Not Receiving Dopaminergic Therapy

Sponsor: S1B1A Neurosciences and the Parkinson Study Group

Purpose: The purpose of this trial to treat patients with early Parkinson's Disease. Patients will be treated with varying doses of a nicotinic agonist looking at both symptomatic motor effect and memory enhancement.

Principal Investigator: Joseph Friedman, MD

Patients Recruited: People with Parkinson's Disease not receiving Dopaminergic drugs. MMSE must be >24 . May be on Eldepryl. No agonists, amantadine, antidepressants, or neuroleptics.

Intervention: varying doses of S1B-1508Y vs. placebo

Duration of study: 5 weeks

Phase: IIa

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

A Multi-Center, Placebo-Controlled Trial of Melatonin for Sleep Disturbance in Alzheimer's Disease

Sponsor: Alzheimer's Disease Cooperative Study

Purpose: The purpose of this trial to treat Alzheimer's Disease patients who experience sleep disturbances associated with Alzheimer's Disease. Two doses of melatonin will be used to treat sleep disturbances in order to lessen the burden on caregivers and family members.

Principal Investigator: Brian R. Ott, MD

Patients Recruited: Anyone 55 years or older with a diagnosis of probable Alzheimer's Disease experiencing sleep disturbances.

Intervention: Two doses of Melatonin vs. placebo

Duration of study: 12 weeks

Phase: III

Site: Alzheimer's Disease & Memory Disorder Clinic, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Michael Pimental, MA, phone (401) 729-3752

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Rhode Island does not have a procedure for certification of specialization by lawyers.

Earlier vs. Later Levo-dopa in Parkinson's Disease (ELLDOPA)

Sponsor: NIH and the Parkinson Study Group

Purpose: Joseph Friedman, MD, is conducting this trial to compare the effect of early or late treatment of Parkinson's Disease with L-Dopa to answer the question of whether L-Dopa slows or hastens the progression of Parkinson's Disease.

Patients Recruited: Patients must be 30 years or older, must be diagnosed with Parkinson's Disease within the last 2 years. No eldepryl, L-DOPA, amantadine, anticholinergics, antihistamines, antidepressants, or benzodiazepines for previous 30 days.

Intervention: varying doses of Carbidopa/Levodopa vs. placebo

Duration of study: 9 months

Site: Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St, Pawtucket, RI 02860

Contact: Margaret Lannon, RN, MS, phone (401) 729-3750

A Phase III Multicenter, Double-Blind, Parallel-Group Placebo Controlled Study of the Effect of Riluzole 50 mg BID or 100 mg BID for Two Years on the Progression of Parkinson's Disease in 1050 Patients

Sponsor: Rhône-Poulenc Rorer

Purpose: The purpose is to treat recently diagnosed patients with the drug Riluzole, in order to study the effect this drug has on delaying the progression of Parkinson's Disease.

Principal Investigator: Joseph H. Friedman, MD

Patients Recruited: Patients must have recently diagnosed Parkinson's Disease with symptoms present for no more than 3 years and must currently be receiving no medications to treat Parkinson's Disease.

Intervention: Two doses of Riluzole or Placebo

Duration of Study: 2 years

Phase: III

Site(s): Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Margaret C. Lannon, RN, MS; phone: (401) 729-3750

Parkinson Disease Collaborative Study of Genetic Linkage (PROGENI)

Sponsor: NIH and the Parkinson Study Group

Purpose: The purpose of this study is to explore genetic, environmental and other factors which may play a role in the development of Parkinson's Disease.

Principal Investigator: Joseph H. Friedman, MD

Patients Recruited: Looking for sibling pairs (brothers and/or sisters) who both have Parkinson's Disease or suspected Parkinson's Disease. Siblings need NOT live in Rhode Island.

Intervention: None

Duration of Study: One visit

Site(s): Movement Disorder Unit, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Margaret C. Lannon, RN, MS; phone: (401) 729-3750

Olanzapine Versus Risperidone and Placebo in the Treatment of Psychosis and Associated Behavioral Disturbances in Patients with Dementia

Sponsor: Eli Lilly and Company

Purpose: The purpose is to determine whether treatment of persons with psychosis and behavioral disturbance related to Alzheimer's Disease or vascular dementia benefit from treatment with Olanzapine or Risperidone.

Principal Investigator: Brian R. Ott, MD

Patients Recruited: Patients must be greater than 40 years old and have hallucinations or delusions associated with dementia caused by Alzheimer's Disease or stroke.

Intervention: Olanzapine, Risperidone, or Placebo

Duration of Study: 28 weeks

Phase: III

Site(s) Alzheimer's Disease and Memory Disorder Clinic, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Michael Pimental, MA; phone: (401) 729-3752

A Randomized, Double-Blind Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Viatmin E and Donepezil HC1 (Aricept®) to Delay Clinical Progression to Alzheimer's Disease (AD) from Mild Cognitive Impairment (MC)

Sponsor: Alzheimer's Disease Cooperative Study and Pfizer/Elsai

Purpose: The purpose is to determine whether treatment of persons with mild forgetfulness can prevent the actual development of Alzheimer's Disease or slow the progression of Alzheimer's Disease

Principal Investigator: Brian R. Ott, MD

Patients Recruited: Patient must be 55 to 90 years of age and have memory difficulties that are not severe enough to interfere with carrying out one's usual daily activities (Mini-Mental=24-30). Must be willing to take only vitamin supplement provided.

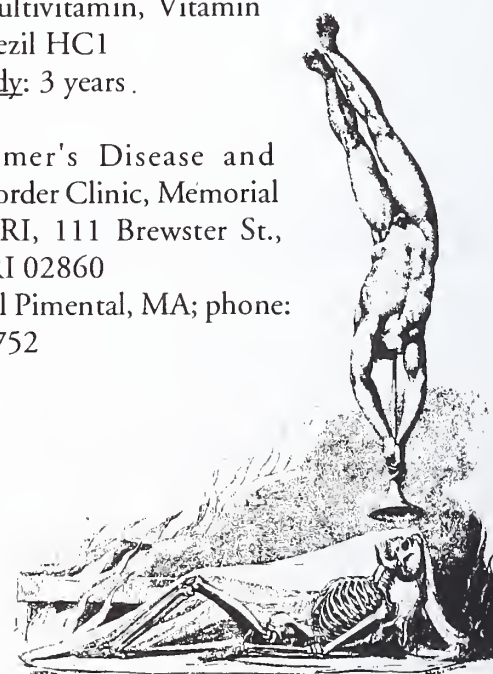
Intervention: Multivitamin, Vitamin E, or Donepezil HC1

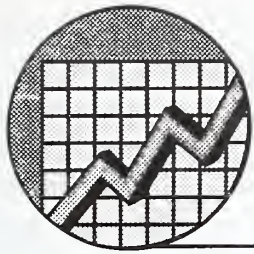
Duration of Study: 3 years

Phase: III

Site(s): Alzheimer's Disease and Memory Disorder Clinic, Memorial Hospital of RI, 111 Brewster St., Pawtucket, RI 02860

Contact: Michael Pimental, MA; phone: (401) 729-3752





Vital Statistics

Rhode Island Department of Health

Patricia A. Nolan, MD, MPH, Director of Health

Edited by Roberta A. Chevoya

Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

Vital Events			
	Reporting Period		
	June 1998	12 Months Ending with June 1998	
	Number	Number	Rates
Live Births	1,204	13,230	13.4*
Deaths	722	9,786	9.9*
Infant Deaths	(10)	(99)	7.5#
Neonatal deaths	(8)	(77)	5.8#
Marriages	922	7,632	7.7*
Divorces	218	3,310	3.3*
Induced Terminations	396	4,864	367.6#
Spontaneous Fetal Deaths	87	967	73.1#
Under 20 weeks gestation	(84)	(896)	67.7#
20+ weeks gestation	(3)	(71)	5.4#

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death				
	Reporting Period			
	December 1997	12 Months Ending with December 1997		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	321	3,280	331.2	3,759.5
Malignant Neoplasms	227	2,496	252.1	7,364.5
Cerebrovascular Diseases	58	689	69.6	775.0
Injuries (Accident/Suicide/Homicide)	24	324	32.7	6,606.0**
COPD	38	433	43.7	355.0***

Excludes two deaths of unknown age *Excludes one death of unknown age

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 990,225

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.



Judicial Diagnosis

Treating Children of Jehovah's Witnesses

Donald T. Ridley, JD

Jehovah's Witnesses are a Christian religious group with a high regard for marriage and family life. In matters of child rearing, Witness parents take their responsibilities seriously and actively involve themselves in all aspects of their children's lives. When it comes to their children's health, Witness parents freely and readily seek good medical care. However, in seeking health care for themselves and their children, the Witnesses strive to obey the Scriptural directive, originally given to the first century Christians, to "keep abstaining . . . from blood."¹ The gravity of this directive can be seen from the fact that the same passage also exhorts Christians to keep abstaining from fornication and idolatry.

The Witnesses' refusal of allogeneic blood can create challenges when a doctor believes transfused blood may be necessary to preserve a child's life or health. Can parents refuse necessary treatment for their children? What is a doctor legally required to do in such cases? This article will attempt to answer these questions on the basis of pertinent Rhode Island law.

RESPECT FOR PARENTAL AUTHORITY

Our law and culture have long looked to parents as the natural and rightful decision-makers for their minor children. The U.S. Supreme Court has repeatedly confirmed that "the custody, care and nurture of the child reside first in the parents, whose primary function and freedom include preparation for obligations the state can neither supply nor hinder."² According to the Supreme Court of Rhode Island, the "parent's 'desire for and right to the companionship, care, custody, and management of his or her children' is a fundamental right."³ Consequently, choices about "family life" and "the upbringing of children" are constitutionally protected from "unwarranted usurpation, disregard, or disrespect."⁴ Indeed, it is an express objective of Rhode Island law to "strengthen the family" and to "conserve and strengthen [a] child's family ties whenever possible."⁵

Thus, in matters of dress, grooming, diet, education, recreation, etc., parents have broad discretion in caring for their children. So too in matters of health. Respect for parental oversight is evident in the legal requirement that doctors first obtain a parent's consent before administering medical treatment to a child.⁶ Parents, however, may not lawfully refuse treatment if their refusal will harm their child. Even if the parents' refusal is motivated by their sincerely held religious beliefs, the state's interest in the welfare of the child is paramount.⁷ Thus, parental authority is not absolute. How, though, does the law authorize intrusion into the parent-child relationship when there is a conflict between the parents' choice

of treatment and, in the treating doctor's opinion, the child's life or health?

MEDICAL NEGLECT OF MINOR CHILDREN

Rhode Island's child protection statute says that "a child whose physical or mental health or welfare is harmed or threatened with harm when his or her parent . . . fails to supply the child with adequate . . . medical care" is a "neglected child."⁸ Thus, the determinative factor for intruding into the parent-child relationship in matters of health care is the adequacy of the parents' choice of treatment - not simply whether the parents are refusing recommended or standard care. In the case of Jehovah's Witnesses, the crucial inquiry is the adequacy of the parents' choice of nonblood medical or surgical management of their child's health problem.

If a doctor, after considering the feasibility of and perhaps consulting with other colleagues about managing a Witness child's care by means of alternative nonblood management, still believes only transfusions will adequately treat the child's problem, what is he to do? Pursuant to Rhode Island's child protection statute, "[w]hen any physician . . . has cause to suspect that a child" is a "neglected child" as defined above, "he or she shall report the incident or cause a report thereof" to be made to the Department of Children, Youth, and Families (DCYF).⁹ The doctor's duty to report is a serious one; failure to make a report could result in a fine or imprisonment.¹⁰ Upon receipt of a report of neglect, DCYF will investigate the matter and, if necessary, petition the family court to temporarily remove the child from the parents' care.¹¹

If a petition is filed, at least one of the parents will be served with a summons plainly setting forth the allegations about the inadequacy of the child's care without transfused blood and informing the parent of the time and place where he or she is to appear before the court on the matter.¹² After hearing evidence from both the doctor on behalf of DCYF and the parents and any witnesses they may call to testify about the alleged indispensable need for blood versus the efficacy of any recognized nonblood medical management, the court will render its decision.¹³

CONCLUSION

The Rhode Island Supreme Court has observed that, "[t]he importance of family security and parents' rights to custody and care of their children is well recognized. These rights must be protected and can be disturbed only when statutory procedures are followed."¹⁴ As a matter of fundamental constitutional law, "notice and a hearing are required

before the children can be removed, even temporarily, from the custody of their parents.”¹⁵, according to one federal court of appeals. Thus, in caring for the children of Jehovah’s Witnesses, a Rhode Island doctor must first determine if blood transfusions will be indispensably necessary to adequately treat the child’s infirmity. If, in his professional opinion, the doctor believes blood will be necessary, he must report the matter to DCYF which, after investigation, may petition the family court to override the parents’ choice of nonblood management.

REFERENCES

1. *Acts* 15:29;21;25
2. *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944).
3. *In re Richard John*, 605 A.2d 486, 487 (R.I. 1992).
4. *M.L.B. v. S.L.J.*, 117 S. Ct. 555, 564 (1996).
5. R.I. Gen. Laws §§ 40-11-1; 14-1-2.
6. 61 Am. Jur. 2d *Physicians, Surgeons, and Other Healers* § 178 (1981); *Bowen v. American Hosp. Assoc.*, 476 U.S. 610, 630 (1986) (“it would almost certainly be a tort as a matter of state law to operate on an infant without parental consent”).
7. *Jehovah’s Witnesses v. King County Hosp.*, 278 F. Supp. 488 (W.D. Wash. 1967), *affid per curiam*, 390 U.S. 598 (1968).
8. R.I. Gen. Laws § 40-11-2 (1)(iv); cf. *id.* § 14-1-3(8)(i).
9. *Id.* § 40-11-6(a), (b).
10. *Id.* § 40-11-6.1.
11. *Id.* §§ 40-11-7(a), (c); see also *id.* § 14-1-5(1)(iv) In the event of a medical emergency (which by definition requires immediate action), a doctor may lawfully administer necessary treatment before making a report to DCYF, or, if a report already has been made, before DCYF has completed its

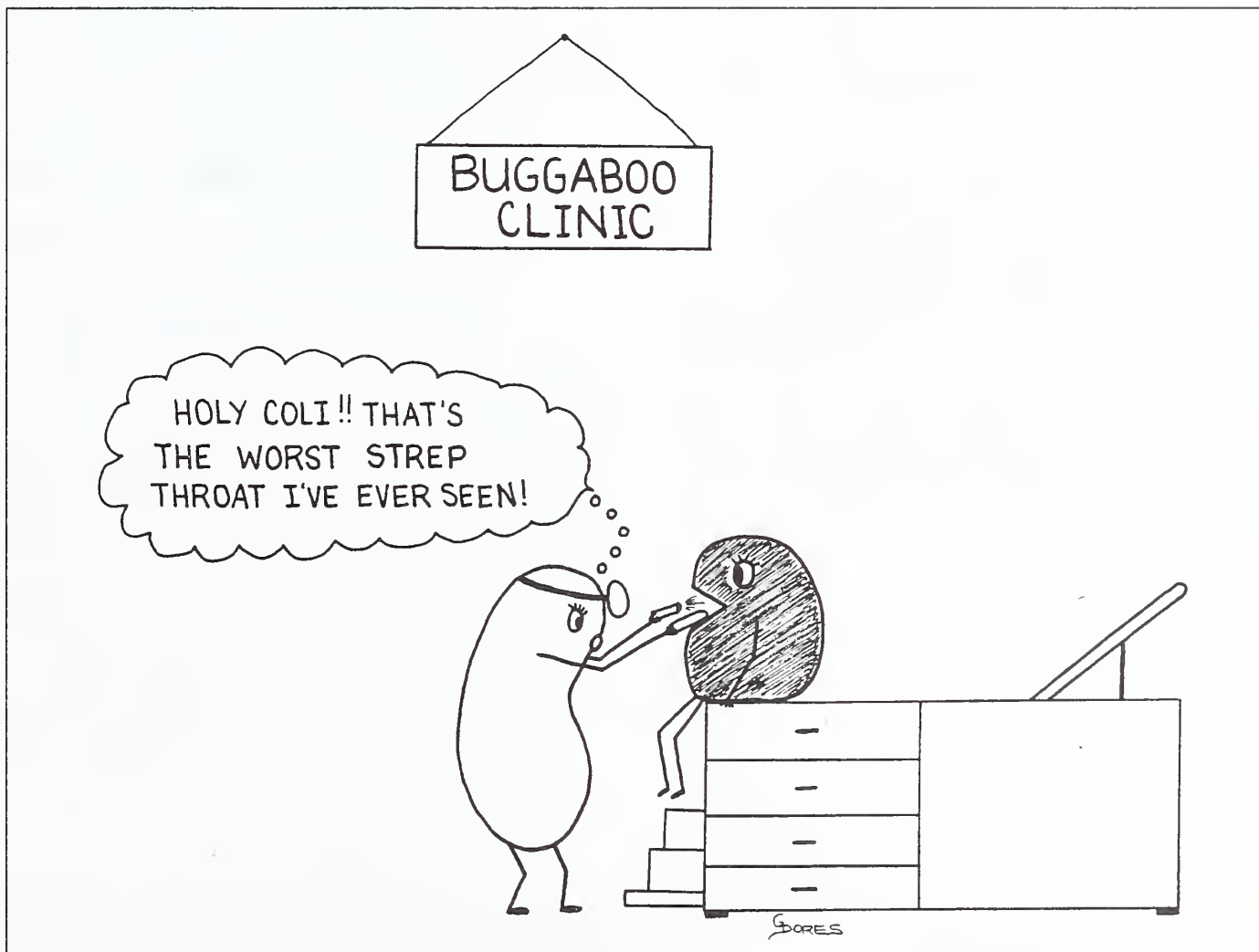
investigation, filed a petition, or obtained a court order. See *Banks v. Medical University of South Carolina*, 444 S.E. 2d 5129 (S.C.1994); cf. *Hodgson v. Minnesota*, 497 U.S. 417, 456-57 (1990) (exception to general requirement of consensus “for those emergencies in which, for example, a parent might delay lifesaving treatment to a child on religious grounds.”).

12. *Id.* §§ 14-1-12, -16, -17.
13. A myth which apparently still has currency amongst some doctors is that a Witness child who receives an unwanted blood transfusion will be abandoned by its parents or condemned by the church. Nothing could be further from the truth. Neither Witness parents who have been unsuccessful in their efforts to obtain nonblood management of their child’s illness nor the child itself has done anything wrong. Rather than shun their child, the parents will continue to lovingly care for and nurture it. *1 Timoth* 5:8, and the congregation will continue to support and encourage the family. *John* 13:34,35.
14. *Desmond v. Brennan*, 639 A.2d 1351, 1353 (R.I. 1994).
15. *Ram v. Rubin*, 118 F.3d 1306, 1311 (9th Cir. 1997).

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NINETY YEARS AGO

❧ [DECEMBER, 1908] ❧

"The physician who undertakes to examine an applicant for life insurance assumes a grave responsibility." Thus begins an article written by Edmund D. Chesebro, MD, on the medical examiner for life insurance and the selection of risks as "practiced in modern scientific life insurance." The article first provides a history of death indemnification beginning in ancient Greece. Then follows a discussion of how annual premiums are determined, based upon existing mortality rates and tables of years of survival per age. The article finally outlines the type of examination to be conducted and what risk factors are to be searched for. These factors include alcoholism, those who are overweight or underweight, and those suspected of tuberculosis, renal disease or arteriosclerosis. The only laboratory procedure recommended is a urinalysis for albumen or sugar. There is no mention of determining blood pressure

or asking about diet as a means of predicting incipient or future disease.

Herbert G. Partridge, MD, discusses heart disease and tuberculosis in relation to pregnancy. Based upon his personal experience [but without providing statistical data] the author concludes that while tuberculosis and pregnancy often coexist, the pregnancy rarely aggravates the symptoms of tuberculosis except for those parturient women with advanced consumption; they do poorly. Similarly, most women with heart disease will go through pregnancy without difficulty.

John E. Donley, MD, presents the case of a 44 year old male with a recent history of weight loss, weakness and back pain. After a few weeks these findings were complicated by incontinence. A diagnosis of spinal cord tumor was made and confirmed by surgery. A second case of autopsy-confirmed suppurative pachymeningitis was described in a 33 year old male.

The minutes of the Rhode Island Ophthalmological and Otological Society are summarized. Cases of trachoma, toxic retrobulbar neuritis, optic trauma and congenital aniridia are presented.

Charles V. Chapin, MD, summarizes the public health data for late summer of 1908. Note is made of an upswing in cases of virulent diphtheria.

FIFTY YEARS AGO

❧ [DECEMBER, 1948] ❧

Stanley A. Wilson, MD, discusses a family of disorders collectively known as berylliosis. The author first summarizes the physical nature of the metal, beryllium, and its uses industrially [particularly in strengthening steel, and in the manufacture of ceramics, x-ray tubes, fluorescent tubes and in various electronic applications.] He notes that beryllium intoxications and granulomatous diseases of the lungs only appeared in the medical literature in 1943 after the element was first widely used. The author then summarizes the clinical evolution, radiological findings and pathological changes in pulmonary berylliosis.

Spinal anesthesia in vaginal deliveries is described by Walter Dufresne, MD, and Howard Umstead, MD. The authors strongly advocate this procedure but only in vaginal deliveries that will not extend more than 90 minutes. It has merit because of the safety of the anesthetic technic, the freedom from labor pains, the diminished fetal asphyxia and freedom from risks of an indwelling catheter. They recommend, though, that it be administered only by those who are aware of its possible dangers and are capable of combatting them.

A case of myxedema and psychosis in a 47 year old woman is presented by James J. Scanlan, MD.

An editorial encourages the use of radiological screening to identify cases of pulmonary tuberculosis.

TWENTY FIVE YEARS AGO

❧ [DECEMBER, 1973] ❧

Motility disturbances of the esophagus are discussed by M.F. Henry Ellis, Jr., MD. He concludes that such disorders are more frequently recognized and their pathophysiology better clarified. Surgical treatment, he states, should be based upon selected cases of hypermotility or hypomotility. Esophagomyotomy, he believes, is useful in diverticula, achalasia, and diffuse esophageal spasm.

James Bobick describes the medical periodicals of Rhode Island particularly those issued by the state medical society.

The Rev. Joseph L. Lennon, OP, provides an essay on his views concerning the moral crisis facing this nation threatening its ethical fabric.

Fred H. Vohr, MD, defines and summarizes the Southern New England Cancer Group and its usefulness, as a regional hospital system, in the management of certain cancer patients.



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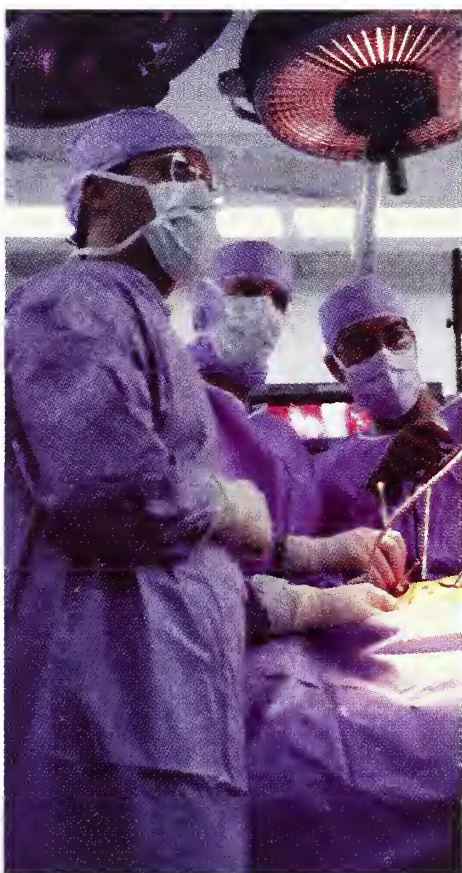


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